UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO

In re: National Prescription Opiate Litigation	)	MDL No. 1:17-md-02804
	)	
THE MUSCOGEE (CREEK) NATION,	)	CASE NO. 1:18-op-45459
	)	
Plaintiff,	)	JUDGE DAN AARON POLSTER
	)	
v.	)	MAGISTRATE JUDGE DAVID A. RUIZ
	)	
PURDUE PHARMA L.P., *et al.*,	)	**REPORT AND RECOMMENDATION**
	)	
Defendants.	)	

On June 9, 2018, Plaintiff Muscogee (Creek) Nation (hereafter "Plaintiff") filed a ten-count First Amended Complaint ("FAC"). (R. 731). On August 2, 2018, the Manufacturer, Distributor, Pharmacy, and Generic Manufacturing Defendants moved to dismiss each count. (R. 933-1, R. 925-1, R. 928-1, R. 929-1). Plaintiff filed an omnibus brief in opposition to the motions on September 28, 2018 (R. 1008). On October 5, 2018, 448 federally recognized Tribes filed an *amici curiae* brief in opposition to Defendants' motions to dismiss. (R. 1026). Defendants filed Reply memoranda on November 2, 2018. (R. 1089, 1086, R. 1087, R. 1090).[1] For the reasons stated below, it is recommended that the motions to dismiss be GRANTED in part and DENIED in part. Specifically, it is recommended that Plaintiff's Lanham Act claim

[1] The manufacturers filed a joint motion to dismiss this action and another case *The Blackfeet Tribe of the Blackfeet Indian Reservation v. AmerisourceBergen Drug Corp., et al.* Likewise, Distributors raise arguments in support of dismissal of this action by reference to their memoranda in support of a motion to dismiss *The Blackfeet Tribe* action. (R. 1128, R. 924, R. 1084).

contained in Count III be DISMISSED as to all Defendants and that Plaintiff's claims against the Generic Manufacturers are partially preempted to the extent they are based on a narrow category of conduct as explained in Section IV-E, *infra*. In all other respects, it is recommended that the motions be DENIED.

I. Fed. R. Civ. P. 12(b)(6)

The principles governing review of a Fed. R. Civ. P. 12(b)(6) motion to dismiss are well-settled. The Sixth Circuit recently reiterated the familiar standards, stating,

> [T]he court "construes the complaint in the light most favorable to the plaintiff, accepts the plaintiff's factual allegations as true, and determines whether the complaint 'contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.'" *Heinrich* [*v. Waiting Angels Adoption Servs., Inc.*, 668 F.3d 393, 403 (6th Cir. 2012)] (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S.Ct. 1937, 173 L.Ed.2d 868 (2009)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft*, 556 U.S. at 678, 129 S.Ct. 1937 (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, 127 S.Ct. 1955, 167 L.Ed.2d 929 (2007)). The plausibility standard "asks for more than a sheer possibility that a defendant has acted unlawfully" but is "not akin to a probability requirement." *Id.* (internal citations omitted). Determining whether a complaint states a plausible claim for relief is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679, 129 S.Ct. 1937.

Berrylane Trading, Inc. v. Transportation Ins. Co., No. 18-3144, 2018 WL 5778298, at *2 (6th Cir. Nov. 2, 2018).

To satisfy the facial plausibility standard and Fed. R. Civ. P. 8(a), a complaint, although not required to plead "detailed factual allegations," cannot rely on "labels and conclusions" or "a formulaic recitation of the elements of a cause of action…." *Bell Atlantic Corp v. Twombly*, 550 U.S. 544, 555 (2007) (internal quotation marks and citations omitted). Rule 8 "demands more than an unadorned, the defendant-unlawfully-harmed-me accusation," and a complaint will not

"suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Iqbal,* 556 U.S. at 678 (quoting *Twombly, 550 U.S. at Id.*, at 557, 557).

As the Sixth Circuit has explained, "[u]nder the familiar rules of notice pleading in federal courts, a complaint should include merely 'a short and plain statement of the claim,' Fed.R.Civ.P. 8(a)(2), and a district court may dismiss a complaint for failure to state a claim 'only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations.'" *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 615 (6th Cir. 2004) (quoting *Swierzkiewickz v. Sorema N.A.*, 534 U.S. 506, 514 (2002); *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984)).

II. The Defendants

The FAC identifies two primary defendant groups. The first is termed the Marketing Manufacturer Defendants[2] (R. 731, PageID# 17076 and ¶¶28-39), with a sub-group termed the Generic Manufacturer Defendants.[3] (¶157). The second group is named Diversion Defendants, which includes three separate groups, identified as Diversion Manufacturer Defendants[4] (PageID# 17076 and ¶¶41-42), Distributor Defendants[5] (PageID# 17076 and ¶¶44-61), and

[2] The "Marketing Manufacturer Defendants" are Purdue Pharma L.P., Purdue Pharma Inc. and The Purdue Frederick Company ("Purdue") (R. 731, ¶¶28-30); Endo Health Solutions Inc. and Endo Pharmaceuticals Inc. ("Endo") (¶¶31-32); Actavis LLC, Actavis Pharma, Inc., Allergan Finance LLC, and Watson Laboratories, Inc. ("Actavis/Allergan") (¶¶33-36); Teva Pharmaceuticals USA, Inc. ("Teva") (¶37); Amneal Pharmaceuticals, Inc. ("Amneal") (¶38); KVK-Tech, Inc. ("KVK") (¶39).

[3] The "Generic Manufacturer Defendants" are Actavis[/]Allergan, Teva, Amneal, and KVK. (¶157).

[4] The "Diversion Manufacturer Defendants" are Amneal and KVK. (R. 731, PageID # 17076).

[5] The "Distributor Defendants" are McKesson Corporation ("McKesson") (¶44); Cardinal Health, Inc. and Cardinal Health 110, LLC ("Cardinal") (¶¶45-46); AmerisourceBergen Corporation and AmerisourceBergen Drug Corporation ("AmerisourceBergen") (¶¶47-48); Morris & Dickson Co., LLC ("Morris & Dickson") (¶49); Walgreen Co. (¶¶50-51), an entity identified in the Complaint as both a Distributor Defendant and a Pharmacy Defendant ("Walgreens") (¶¶66-67) (Walgreens Boots Alliance, Inc. was dismissed from this action (R. 1022); Wal-Mart Stores, Inc. ("Walmart") (¶52), an entity identified in the Complaint as both a Distributor Defendant and a Pharmacy Defendant (¶68); SAJ Distributors ("SAJ") (¶53); GCP Pharma LLC ("GCP") (¶54); Anda Pharmaceuticals, Inc. and Anda, Inc. ("Anda") (¶¶55-56); "Omnicare Distribution Center LLC ("Omnicare") (¶57); Smith Drug Company ("Smith") (¶58); The Harvard Drug Group, LLC ("Harvard") (¶59);"PBA" means Pharmacy Buying Association (¶60); H.D. Smith, LLC ("H.D. Smith") (¶61).

Pharmacy Defendants[6] (PageID# 17076 and ¶¶63-91). The FAC identifies two entities, Amneal Pharmaceuticals, Inc. and KVK-Tech, Inc., within Marketing Manufacturer Defendants (¶38, 39) and its sub-group Generic Manufacturer Defendants (¶157), and within Diversion Manufacturer Defendants. (¶¶41, 42). The FAC joins Diversion Manufacturer Defendants with the Distributor Defendants and Pharmacy Defendants to form the Diversion Defendants group. (¶14). Two entities, Walgreen Co. ("Walgreens") and Wal-Mart Inc. ("Walmart"), are named as both Distributor Defendants and Pharmacy Defendants. (¶¶51, 52, 67, 68). Together, the Marketing Manufacturer Defendants, the Diversion Manufacturer Defendants, the Distributor Defendants and the Pharmacy Defendants are referred to as the Defendants. (R. 731, PageID# 17076).

A. Marketing Manufacturer Defendants

The FAC alleges that each Marketing Manufacturer "has manufactured and distributed substantial amounts of prescription opioids[;]" their respective products "have been and continue to be sold nationwide, including in Oklahoma, where Plaintiff is located" (¶¶28-39); and each "has made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain." (¶40). Moreover, the FAC alleges each Marketing Manufacturer

[6] The "Pharmacy Defendants" are CVS Pharmacy, Inc., and Oklahoma CVS Pharmacy, LLC ("CVS") (¶¶63-65) (CVS Health Corporation was dismissed from this action (R. 1023); Walgreen Co. ("Walgreens") (¶¶66-67) (the Complaint identifies Walgreens a both a Pharmacy Defendant and a Distributor Defendant) (¶¶50-51) (Walgreens Boots Alliance, Inc. was dismissed from this action (R. 1022); Wal-Mart Stores, Inc. ("Walmart") (¶68) (identifies Walmart as both a Pharmacy Defendant and a Distributor Defendant) (¶52); The Drug Warehouse ("Drug Warehouse") (¶69); May's Drug Store ("May's") (¶70); Reasor's LLC ("Reasor's") (¶71); Med-X Corporation ("Med-X") (¶72); Economy Discount Pharmacy, Economy Pharmacy, Inc. and Economy Pharmacy Express ("Economy") (¶73-75); City Drug Co. and City Drug of Coweta, Inc. ("City Drug") (¶¶76-77); Spoon Drugs, Inc. ("Spoon") (¶78); Carefirst Pharmacy, Inc. ("Carefirst") (¶79); Cityplex Pharmacy "Cityplex" (¶80); Couch Pharmacy on Sheridan ("Couch") (¶81); Ernie's Pharmacy & Wellness Center, Inc. ("Ernie's") (¶82) Freeland Brown Pharmacy, Inc. ("Freeland") (¶83); Gaddy Discount Drug, Inc. ("Gaddy") (¶84); Getman-Apothecary Shoppe, Inc. ("Getman") (¶85); Langsam Health Services, LLC ("Langsam") (¶86); M & D Star Drug, Inc. ("M&D") (¶87); Med-Econ Drug, Inc. ("Med-Econ") (¶88); Olympia Pharmacy ("Olympia") (¶89);Pippenger Pharmacies LLC ("Pippenger") (¶90); Rogers Drug Co. Inc. ("Rogers") (¶91).

Defendant "in violation of their legal obligations…has made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain." (¶40).

B. Generic Manufacturer Defendants

The FAC identifies the following Marketing Manufacturer Defendants as part of a Generic Manufacturer Defendants sub-group: Activis[/]Allergan, Teva, Amneal, and KVK. (¶157). The FAC alleges, *inter alia,* that "rather than act in accordance with their duties, Generic Marketing Manufacturer Defendants aggressively marketed their generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase their own market share among generics." Of the four Generic Manufacturer Defendants, the FAC identifies only Activis/Allergan and Teva as entities that maintain both branded and generic product lines (¶¶33-37) and alleges that "[t]hose Marketing Manufacturer Defendants that manufactured and sold generic prescription opioids in addition to name-brand prescription opioids knew and intended their wrongful marketing conduct alleged herein would increase the sales and profits of both their name-brand and generic prescription opioids." (¶155).

C. Diversion Defendants

1. Diversion Manufacturer Defendants

The FAC identifies Amneal and KVK as the Diversion Manufacturer Defendants (¶¶41-42), and alleges each "has consistently failed to comply with its legal obligations concerning prescription opioid diversion." (¶43).

2. Distributor Defendants

Plaintiff alleges each Distributor Defendant have "consistently failed to comply with its legal obligations concerning prescription opioid diversion." (¶62). The FAC also alleges that

"McKesson, Cardinal, AmerisourceBergen, Walgreens, and Walmart have paid civil penalties to resolve government allegations regarding prescription opioid diversion." (*Id.*).[7]

3. Pharmacy Defendants

Plaintiff alleges each Pharmacy Defendant "has sold and continues to sell prescription opioids at locations in Oklahoma that serve [Muscogee] Nation citizens, including in close proximity to [Plaintiff's] hospitals, clinics, and other healthcare facilities serving patients of [Plaintiff's] healthcare system" (¶¶63-91). In addition, the FAC claims that "each Pharmacy Defendant has consistently failed to comply with its legal obligations concerning prescription opioid diversion [and] each Pharmacy Defendant has paid civil penalties to resolve government allegations regarding prescription opioid diversion." (¶92).

D. The claims against the Defendants

1. Claims against the Marketing Manufacturer Defendants

The FAC asserts the following claims against the Marketing Manufacturer Defendants (including the Generic Manufacturing Defendants):

- COUNT I, Violation of RICO, 18 U.S.C. § 1961 *et seq*., Opioid Marketing Enterprise (Against the Marketing Manufacturer Defendants) (¶¶ 353-379);
- COUNT II, Violation of RICO, 18 U.S.C. § 1961 *et seq*., Opioid Supply Chain Enterprise (Against All Defendants) (¶¶380-408);
- COUNT III, Lanham Act (Against All Defendants) (¶¶409-418);
- COUNT IV, Nuisance (Against Marketing Manufacturer Defendants) (¶¶419-432);
- COUNT V, Negligence and Negligence Per Se (Against Marketing Manufacturer Defendants) (¶¶433-445);

[7] McKesson, Cardinal and AmerisourceBergen are alleged to have "distributed substantial amounts of prescription opioids *in Oklahoma and the [Muscogee] Nation.*" (¶¶44-48) (emphasis added). The remaining Distributor Defendants are alleged to have "distributed substantial amounts of prescription opioids *in Oklahoma, where the [Muscogee] Nation is located."* (¶¶49-61) (emphasis added).

- COUNT VI, Unjust Enrichment (Against Marketing Manufacturer Defendants) (¶¶446-450);
- COUNT X, Civil Conspiracy (Against All Defendants) (¶¶485-493).

2. Claims against the Diversion Defendants

The FAC asserts the following claims against the Diversion Defendants (the Distributors, Pharmacies, and Diversion Manufacturing Defendants):

- COUNT II, Violation of RICO, 18 U.S.C. § 1961 *et seq*., Opioid Supply Chain Enterprise (Against All Defendants) (¶¶380-408);
- COUNT III, Lanham Act (Against All Defendants) (¶¶409-418);
- COUNT VII, Nuisance (Against Diversion Defendants) (¶¶451-464) ;
- COUNT VIII, Negligence and Negligence Per Se (Against Diversion Defendants) (¶¶465-478);
- COUNT IX, Unjust Enrichment (Against Diversion Defendants) (¶¶479-484);
- COUNT X, Civil Conspiracy (Against All Defendants) (¶¶485-493).

This Report and Recommendation refers to the Marketing Manufacturer Defendants as the "Manufacturers;" to the "Generic Marketing Manufacturer Defendants" as "Generic Manufacturers;" to the Diversion Manufacturer Defendants as "Diversion Manufacturers;" to the Distributor Defendants as "Distributors;" to the Pharmacy Defendants as "Pharmacies;" to the Diversion Defendants by that term; and to all of them collectively as "Defendants."

III. Factual Allegations in the FAC[8]

A. The Increase in Opioid Use/Abuse and Overdose Deaths

As early as 1996, it is alleged Manufacturers began to disseminate misleading information regarding both brand-name and generic prescription opioids (R. 731, ¶¶106-107), waging an "aggressive" and "massive marketing campaign to misstate and conceal the risks of treating chronic pain" with those drugs. (¶¶1, 4-5). Even when used properly, it is alleged opioids can cause addiction and overdose, risks that are amplified when "used to treat chronic pain, or when used for non-medical purposes." (¶1). By misstating and/or concealing those risks, Manufacturers overcame "the longstanding medical consensus that opioids were unsafe for the treatment of chronic pain," resulting in a fourfold increase between 1999 and 2016 of both the number of opioids prescribed nationally as well as the number of deaths resulting therefrom. (¶5).

The FAC alleges that American Indians suffer "the highest per capita rate of opioid overdoses." (¶¶15-16). The impact of opioid use and abuse on American Indian children, pregnant women, and infants who may experience "opioid withdrawal and Neonatal Abstinence Syndrome" is alleged to be "particularly devastating." (¶¶17-19). The FAC cites a CDC report to allege that "approximately one out of every 14.5 American Indian youths aged 12 or older used prescription opioids for non-medical purposes in 2012," a rate that is "60% higher than the rate for white youths." (¶17). It also cites a study of pregnant American Indian women finding that

[8] This report and recommendation provides only a brief overview of the allegations in the nearly 140-page FAC. Further, the substance of the allegations echo those found in another case in this multi-district litigation that were set forth in a previous report and recommendation. *See In re Nat'l Prescription Opiate Litig.*, No. 1:18-OP-45090, 2018 WL 4895856 (N.D. Ohio Oct. 5, 2018), *report and recommendation adopted in part, rejected in part*, No. 1:17-MD-2804, 2018 WL 6628898 (N.D. Ohio Dec. 19, 2018). Hereafter, the court refers to that report and recommendation and ensuing decision collectively as "*Summit County*," but citations to specific portions of those opinions utilize the court docket's record/document ("R.") and page identification (PageID#) numbering systems. While the allegations in the *Summit County* complaint were significantly lengthier than in the FAC, the court reiterates only the general allegations herein and focuses more on those allegations unique to the case at bar.

group "up to 8.7 times more likely than pregnant women from other groups to be diagnosed with opioid dependency or abuse, and in some communities more than one in 10 pregnant American Indian women have a diagnosis of opioid dependency or abuse." (¶19). Further, the FAC alleges studies demonstrate that "Oklahoma, where the vast majority of [Plaintiff]'s citizens reside, leads the country in opioid abuse" (¶7), and cites DEA data "show[ing] that in 2016, Oklahoma has seen annual distribution exceeding 600 milligrams per resident, and 5,923 milligrams per opioid user." (¶266).

B. Allegations of an Intentional Campaign to Increase Opioid Use

1. Nine Categories of Misrepresentation

Manufacturers are alleged to have engaged in a multi-million dollar marketing campaign that made nine categories of misrepresentations downplaying the risks of addiction and exaggerating the benefits of opioids: (1) the risk of addiction is rare; (2) addiction risk is manageable even for patients with a history of drug abuse; (3) signs of opioid addiction are actually attributable to untreated pain, termed "pseudoaddiction" requiring additional opioids; (4) withdrawal can be managed easily; (5) increased dosing does not result in significant risks; (6) long-term use of opioids for pain improves the ability to function; (7) the risks of alternative pain treatments outweigh any adverse effects of opioids; (8) addiction is prevented by time-released dosing; and (9) the development of abuse-deterrent opioid products provided a solution to opioid abuse. (¶298; *see also* ¶¶ 102-110, 116-118, 120-125). Each of the Manufacturers is alleged to have "made misstatements or omitted information regarding the risks of using prescription opioids to treat chronic pain" (¶40), using "websites, promotional materials, conferences, guidelines for doctors, and other vehicles suggesting that the risk of addiction when opioids are used for chronic pain was low – statements directly contrary to established scientific evidence."

(¶103). It is alleged that Manufacturers' scheme was designed to influence doctors' prescribing habits (¶¶132-133); to reach "susceptible patients like veterans and the elderly," and to target primary care physicians who generally were "less aware of medical literature regarding the dangers of treating chronic pain with opioids." (¶¶135-136). Manufacturers' alleged fraudulent marketing scheme was motivated by financial gain. (¶¶105, 125, 296, 320, 328).

The FAC further claims that Manufacturers, who produced name-brand, generic opioids, or both, intended their wrongful marketing conduct to increase sales and profits of both product lines. (¶¶105, 125, 155, 296, 320, 328). It is alleged that Generic Manufacturers, "aggressively marketed their generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase their own market share…" (¶160). Plaintiff alleges that Manufacturers' failure to exercise reasonable care in marketing and selling opioids is proscribed by common law, state law, and federal law. (¶¶96-101).

2. The Use of Front Groups and Key Opinion Leaders

It is alleged that not only did Manufacturers disseminate deceptive information about opioids directly to doctors and patients, but that they also utilized a number of "nominally independent, neutral" professional organizations to spread the "pro-opioid" message, concealing the fact that those front groups were funded and controlled by them, and acted for their benefit. (¶¶104-106). Their alleged activities included efforts "to limit prescriber accountability," criticism of CDC opioid prescribing guidelines, formulation and distribution of guidelines and articles that "misleadingly downplayed" the risks of opioid use and promoted the drugs as "safe and effective"— publications to which Manufacturers contributed content as well as sponsorship. (¶¶105, 121, 130-131, 299-318). Manufacturers also allegedly recruited and "heavily funded" pain management physicians to serve as ostensibly objective "Key Opinion Leaders" ("KOLs"),

who would spread the nine categories of misrepresentations to fellow physicians, taking advantage of the great confidence physicians place on "seemingly independent peers." (¶127). These KOLs were "under the practical control of, and/or for the benefit of, the Marketing Manufacturer Defendants and the creation of an increased market for opioids that would yield higher revenue and profits." (*Id.*). Plaintiff alleges that "Manufacturers' support helped the KOLs become respected industry experts" who rose to prominence and "falsely promoted the benefits of using opioids to treat chronic pain, repaying the [Manufacturers] by advancing their marketing goals." (¶302).

The FAC alleges that Manufacturers knew their statements were misleading because: (1) they were contrary to established fact, and (2) they were fined or sanctioned by various government entities for their actions. (¶¶138-142). In the course of settling legal actions, certain Manufacturers acknowledged that representations made to some health care providers were "inconsistent with the FDA-approved prescribing information" and "agreed to halt misleading advertisements [] about the safety of opioids." (¶¶139-142).

C. Distribution and Sales Allegations

Plaintiff alleges that all Defendants were required to register and comply with duties imposed by the Federal Controlled Substances Act ("CSA") and its Regulations, which requires manufacturers and distributors alike to maintain controls against diversion of both brand-name and generic opioids, and to employ a monitoring system to help identify and report suspicious orders to the DEA (R. 731, ¶¶166-169). It also requires pharmacies to review the validity of controlled substance prescriptions prior to dispensing. (¶¶170-177). Further, each Diversion Defendant is alleged have both common law and statutory duties of reasonable care. (¶¶162, 178-199)). It is alleged that all Defendants were aware of their anti-diversion duties.

Regarding sales, distribution, and dispensing, the FAC alleges the DEA provides guidance, and advice in briefings, conferences, and letters to make manufacturers and distributors aware of their "legal, regulatory, and due diligence responsibilities." (¶¶200-205). It further alleges that the Distributor Defendants were on notice that their own industry group, the Healthcare Distribution Alliance ("HDA"), published guidelines for reporting suspicious orders and preventing diversion. (¶¶206-207). It is alleged that the DEA, state pharmacy boards, and national industry associations also provided "extensive guidance to pharmacists" regarding the means of determining the legitimacy of a prescription, how to resolve "red flags" signaling problems with a prescription, and what to do if those "red flags" cannot be resolved. (¶¶237-239). "Despite knowing the risks of diversion and their broad assurances to regulators, states and the public," some of Distributors paid millions of dollars in multiple actions that alleged failures to abide by their anti-diversion obligations. (¶¶212-223). All of the Distributors, including the Diversion Manufacturer Defendants, are alleged to have "recklessly or negligently" allowed diversion. (¶¶212, 224-229). It is alleged that "[d]espite knowing and even warning of these risks [that attend filling suspicious prescriptions], Pharmacy Defendants recklessly or negligently permitted diversion to occur." (¶245). The Pharmacies are alleged to have been on notice "because of their history of being penalized for violating their duties in other jurisdictions," citing instances in which certain Pharmacies paid significant fines and settlements for failure to comply with record keeping and dispensing requirements (¶¶251, 253-254, 256); for failure to monitor opioid use by at-risk Medicaid patients (¶255); and for filling prescriptions "with no legitimate medical purpose," that were "clearly forged," or "signed by prescribers with invalid DEA registration numbers." (¶¶247-250, 252).

The FAC alleges that "Defendants jointly agreed to disregard their statutory duties to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market," while feigning compliance in order to conceal their misconduct. (¶¶143-144, 330-332). Participation in the HDA allegedly provided an opportunity for the Defendants "to flout the closed system designed to protect citizens" by publicly announcing formulation of industry anti-diversion guidelines—measures with which privately "none of them complied." (¶330). Plaintiff also alleges that Pharmacies made public statements that "acknowledged these risks [of filling prescriptions for non-medical purposes] and assured the public that issues affecting public health and safety [were] their highest priority," which statements are alleged to be "misrepresentations about their activities [that] constituted concealment of their wrongdoing." (¶¶237, 240-244). Purdue, for example, is alleged to have concealed data it collected identifying suspicious health care providers, but filled those prescriptions rather than reporting them. (¶¶143-144, 146-148).

Defendants allegedly conspired to increase DEA quotas in order to "benefit collectively from a greater pool of prescription opioids." (¶¶332). "[F]or more than a decade, Defendants worked together in an illicit enterprise, engaging in illegal conduct with the common purpose and achievement of vastly increasing their respective profits and revenues by exponentially expanding a market that the law intended to restrict." (¶329).

D. Allegations of Harms Suffered by Plaintiff

The FAC alleges that "Defendants' misleading marketing and failure to prevent prescription opioid diversion damaged [Plaintiff] and its citizens" contributing to a "range of social problems, including violence and delinquency, . . . child neglect, family dysfunction, babies born addicted to opioids, criminal behavior, poverty, property damage, unemployment,

and social despair. As a result, more of [Plaintiff's] resources are devoted to addiction-related problems." (¶ 294). Citing an economist's study, it is alleged that "opioids may be responsible for roughly 20% of the national decline in workforce participation by prime-age men and 25% of the drop by women." (¶267).

IV. Analysis

A. Statute of Limitations

Manufacturers contend that Plaintiff's claims are time-barred to the extent that the complaint, filed April 3, 2018, is based on alleged injuries arising from Defendants' misrepresentations that occurred prior to the two-year to four-year limitation periods that govern the asserted causes of action. (R. 933-1, PageID# 21269-21270). Plaintiff maintains that common law tolling doctrines apply to suspend the commencement of the various limitation periods and further argues that it is immunized from the operation of statutes of limitation by the *nullum tempus occurit regi* doctrine. (R. 1008, PageID# 23998-24010).

A motion seeking dismissal on statute of limitations grounds may be resolved as a matter of law if undisputed facts establish that the claims are time barred. *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 547 (6th Cir. 2012), *cert. denied,* 568 U.S. 1157 (2013). Under Oklahoma law, a discovery rule tolls the commencement of a limitation period "until the injured party knows or, in the exercise of reasonable diligence, should have known of the injury." *Calvert v. Swinford*, 382 P.3d 1028, 1033 (Okla. 2016); *Digital Design Grp., Inc. v. Info Builders, Inc.*, 24 P. 3d 834, 840-841 (Okla. 2001) (noting that the discovery rule may apply to situations in which the injury was concealed from or unlikely to come to plaintiff's attention); *Wing v. Lorton*, 261 P.3d 1122, 1126 n.1 (Okla. 2011) (explaining that where claims involve a continuing or repeated wrong,

"the statute does not begin to run until the wrong is over and done with") (internal quotations and citations omitted).

Plaintiff alleges that Manufacturers concealed their consistent failure to comply with anti-diversion duties and jointly agreed with other Defendants to disregard those duties while maintaining a false appearance of adherence. (*E.g.*, R. 731, ¶¶14-15, 98, 143-144, 148-149, 227, 330-336). The FAC further asserts that they "engaged and continue to engage in a massive marketing campaign to misstate and conceal the risks of treating chronic pain with opioids," and that "many aspects of the scheme continue to the present." (*E.g.*, ¶¶4, 270, 315). The complained-of failure by Manufacturers to guard against diversion of their brand-name and generic opioid products allegedly "poses a continuing threat to the health, safety, and welfare of [Plaintiff] and its citizens" requiring Plaintiff to bear substantial costs. (*E.g.*, R. 14-15, 278-281, 383, 400, 404, 420, 426, 452).

These allegations are analogous to those pled by the plaintiffs in *Summit County*, whose claims the Manufacturers challenged based on the same arguments asserted here. Accordingly, the court's analysis and conclusion reached in *Summit County* support the same conclusion here. The court finds Plaintiff's allegations sufficiently raise a plausible inference that the applicable statutes of limitations are subject to tolling. (R. 1025, PageID# 24860-24862 as adopted by R. 1203, PageID# 29022-29025).[9]

B. Municipal Cost Recovery Rule

Manufacturers contend that the common law municipal cost recovery rule, also known as the free public services doctrine, bars Plaintiff's claims to the extent that they seek the costs of

[9] Having determined that tolling doctrines suspend the operation of the various statutes of limitations, the court declines to address the issue of whether an Indian tribe may invoke the *nullum tempus* doctrine to override a statute of limitations defense, an issue that the Oklahoma courts have not addressed.

providing government services absent statutory authorization. (R. 933-1, PageID# 21234-21236; R. 1089, PageID# 27226). As in *Summit County*, Plaintiff alleges damages attributable to Defendants' misconduct, including the costs of emergency, law enforcement, and criminal justice services, among others. (R. 731, ¶¶21, 22, 282, 351). Plaintiff further alleges, as in *Summit County*, that the expenses incurred in responding to the opioid epidemic are the consequence of long-term, continuing misconduct by the Defendants. (*E.g.*, ¶¶14, 270, 315, 383, 400, 404, 420, 426, 452). Accordingly, the reasoning and conclusion from *Summit County* apply here, *i.e.*, the rule does not bar recovery under Plaintiff's federal RICO claims, Counts One and Two. (R. 1025, Page ID# 24823-24828).

Manufacturers contend that because Oklahoma law has not expressly rejected the rule, the failure to apply it to Plaintiff's other claims would expand liability under state law, an outcome federal courts are cautioned to avoid. *See, e.g., In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 937 (6th Cir. 2014) (R. 933-1, PageID# 21236; R. 1089, PageID 27224-27225). The decisions they cite apply the rule to preclude recovery by government entities for the costs of addressing discrete occurrences that, even if rare, were reasonably predictable and therefore enabled legislative bodies to provide tax-supported cost recovery if they chose to do so.[10] As such, they differ materially from the facts and circumstances alleged by Plaintiff—ongoing, persistent misconduct necessitating continuous government expenditures.

[10] *See Cty. of Erie v. Colgan Air, Inc.*, 711 F.3d 147 (2d Cir. 2013); *Canyon Country v. Syngenta Seeds, Inc.*, 519 F.3d 969 (9th Cir. 2008); *District of Columbia v. Air Florida, Inc.*, 750 F.2d 1077 (D.C. Cir. 1984); *City of Flagstaff v. Atchison, Topeka & Santa Fe Ry. Co.*, 719 F.2d 322 (9th Cir. 1983); *City of Philadelphia v. Beretta U.S.A., Corp.*, 126 F. Supp. 2d 882 (E.D. Pa. 2000), *aff'd on other grounds*, 277 F.3d 415 (3d Cir. 2002)*; see also United States v. Standard Oil Co.*, 332 U.S. 301(1947).

In concluding that the rule did not bar the plaintiffs' recovery in *Summit County*, the court was persuaded by decisions declining to apply the doctrine to state law tort claims based on the "reasoning that a doctrine that publicly spreads the costs caused by one-time tortfeasors, such as a negligent driver, is inappropriately applied where a defendant engages in a course of repetitive conduct that causes harm of a substantial magnitude and imposes a repeated burden on government services."[11] (R. 1025, PageID# 24825-24828). Manufacturers cite no Oklahoma authority holding otherwise.

Accordingly, the court declines to apply the rule to Plaintiff's state law claims and concludes, pursuant to the prior holding of this court, that the costs of Plaintiff's governmental services are recoverable to the extent that they exceed the ordinary costs of providing those services and if evidence establishes that they were incurred due to the Defendants' violation of state law. (R. 1203, PageID# 29037-29038).

[11] *See Cincinnati v. Beretta U.S.A. Corp.*, 768 N.E.2d 1136, 1149-1150 (Ohio 2002); *City of Boston v. Smith & Wesson Corp.*, 2000 WL 1473578, *8 (Mass. Super. Ct. 2000); *James v. Arms Tech., Inc.* 820 A.2d 27, 48-49 (N.J. App. Div. 2003); *In re Opioid* Litigation, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018); see *also Flagstaff,* 719 F.2d at 324 (recognizing that cost recovery is permitted where "the acts of a private party create a public nuisance which the government seeks to abate"). (R. 1025, PageID# 24825-24827 & nn. 14-17).

C. Federal RICO Claims – Counts I and II[12]

Plaintiff pleads two claims pursuant to the Racketeer Influenced and Corrupt Organizations (RICO) Act § 1961 *et seq.* Count I asserts civil RICO violations against the Marketing Manufacturer Defendants who, joined by front groups and KOLs, formed an association-in-fact "Opioid Marketing Enterprise" that they used "to engage in a scheme to increase their profits and sales unlawfully, and grow their share of the prescription painkiller market, through repeated and systematic misrepresentations about the safety and efficacy of opioids for treating long-term, chronic pain," which "fueled the opioid epidemic in the United States." (R. 731, ¶¶296-297, 353-379). All Defendants are alleged to have operated an association-in-fact "Opioid Supply Chain Enterprise" that was "formed for the purpose of unlawfully increasing sales, revenues, and profits by fraudulently increasing the quotas set by the DEA that would allow them to benefit collectively from a greater pool of prescription opioids….jointly agree[ing] to disregard their statutory duties to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market" and through that enterprise created the opioid epidemic. (¶¶332, 399, 404, 380-408). The FAC also alleges that the Defendants were filling suspicious orders on a "daily basis-leading to the

[12] Manufacturers refer to Manufacturers' Joint Summit County Memorandum of Law (MOL) (R. 499-1) §§ II.B.2 & III.B.2 (pp. 11-17 and 29-30 addressing causation as to each of the RICO counts). Distributors address predicate acts only in their Muscogee Joint MOLs (Moving and Reply) and refer to the RICO arguments in their Blackfeet Joint MOLs (R. 924 and 1084 - moving and reply). Distributors also refer to the causation (direct injury) argument in Distributors Joint Summit County MOL (R. 491-1) § I.B. The Pharmacies incorporate by reference both Manufacturers' and Distributors' Muscogee Joint MOLs and also refer to the RICO causation arguments in the Pharmacies' Broward County MOLs (moving and reply). The Generic Manufacturers "adopt and incorporate" Manufacturers' Joint Muscogee/Blackfeet MOL. The Generic Manufacturers refer specifically to the RICO causation sections of Manufacturers Joint Muscogee/Blackfeet MOL at §§ I, II.C, V.A.2 and to Manufacturers' Joint Summit County MOL (R. 499-1) pp. 28-34; they also refer to Manufacturers' Muscogee/Blackfeet MOL arguments asserting that Plaintiffs impermissibly seek to enforce CSA in the RICO Supply Chain Count and in all state law claims citing Manufacturers' Joint Muscogee/Blackfeet MOL § II.A.F, Manufacturers' Joint Summit MOL (R. 499-1) pp. 27-28, 47-48, and Distributors' Joint Summit MOL pp. 36-38 (R. 491-1).

diversion of hundreds of millions of doses of name-brand and generic prescription opioids into the illicit market." (¶395).

The RICO Act authorizes a civil cause of action to be brought in any appropriate federal district court by "[a]ny person injured in his business or property by reason of" conduct prohibited by RICO's substantive provisions, and provides for recovery of treble damages, costs and reasonable attorney's fees. 18 U.S.C. § 1964(c). A claim under § 1964(c) may proceed "if the defendant engages in a pattern of racketeering activity in a manner forbidden by these provisions, and the racketeering activities injure the plaintiff in his business or property." *Sedima, S.P.R.L. v. Imrex Co.,* 473 U.S. 479, 495 (1985). To survive dismissal, a civil RICO claimant also is required to demonstrate that a defendant's alleged wrongful conduct was the proximate cause of an alleged direct injury to business or property that confers standing to sue. The Sixth Circuit explained,

> Like the antitrust laws, RICO's civil-suit provision imposes two distinct but overlapping limitations on claimants—standing and proximate cause. Standing poses a threshold question involving constitutional, prudential and (as in this case) statutory limitations on who may sue, regardless of the merits of that person's claim. *See Allen v. Wright,* 468 U.S. 737, 750–51, 104 S.Ct. 3315, 82 L.Ed.2d 556 (1984) ("In essence the question of standing is whether the litigant is entitled to have the court decide the merits of the dispute or of particular issues.") (quotation omitted). Proximate cause poses a merits question involving common-law and prudential limitations on the consequences for which the law will hold a defendant accountable, regardless of the plaintiff's standing to sue.

Trollinger v. Tyson Foods, Inc., 370 F.3d 602, 612 (6th Cir. 2004). As instructed by Supreme Court precedent, courts read the terms of the RICO Act "broadly," *Sedima*, 473 U.S. at 497, and construe the Act "liberally." *Boyle v. United States*, 556 U.S. 938, 944 (2009), *Ouwinga v. Benistar 419 Plan Servs., Inc.,* 694 F.3d 783, 794 (6th Cir. 2012) (noting "the statutory requirement of liberal construction to effectuate RICO's remedial purposes").

1. Previously Addressed Arguments

The Defendants charge that Plaintiff's RICO claims fail because they do not adequately plead the following: (1) standing, (2) causation, (3) the existence of an enterprise, and (4) predicate acts. They further contend that the FAC fails to satisfy Fed. R. Civ. P. Rule 9(b)'s particularity requirement or to sufficiently differentiate among the Defendants with respect to their allegations.[13] Previously in this MDL, the court had occasion to address all these arguments when addressing the motions for dismissal in *Summit County*. (R. 1025 & 1203). The issue of RICO standing, including whether an injury to business or property was alleged or whether the plaintiffs' injuries were based on personal injuries, was addressed in detail. (R. 1025, PageID# 24818-24830, *adopted by* R. 1203, PageID# 29029-29039). Causation (R. 1025, PageID# 24830-24842), the existence of an enterprise (*Id*., PageID# 24842-24845), and predicate acts[14] were also addressed. (*Id*., PageID# 24845-24854). The court also rejected the Rule 9(b) arguments, observing that "courts have relaxed Rule 9(b)'s heightened pleading requirements in cases involving complex fraudulent schemes or those occurring over a lengthy period of time and involving thousands of billing documents." (R. 1025, PageID# 24845, quoting *In re U.S. Foodservice Inc. Pricing Litig.*, 2009 WL 5064468, at *18 (D. Conn. Dec. 15, 2009)). The Defendants either did not object to the court's recommendations or their objections were overruled. (R. 1203).

After reviewing the Defendants' briefs and replies herein, the court finds nothing materially new in these arguments. Given that Plaintiff's FAC tracks the allegations in Summit

[13] *See* R. 933-1 and R. 1089 (Manufacturers); R. 925-1, R. 1086, R. 924, and R. 1084 (Distributors); R. 928-1 and R. 1087 (Pharmacies); R. 929-1 and R. 1090 (Generic Manufacturers).

[14] Because the court finds that sufficient predicate acts have otherwise been plead, the viability of Plaintiff's novel theory—that violations of the Oklahoma Consumer Protection Act and Oklahoma Controlled Substances Act constitute predicate acts under RICO by being boot strapped to the Travel Act, 18 U.S.C. § 1952—need not be resolved. (R. 731, ¶¶387-393)

County, the court sees no reason to reiterate in any detail its recommendation that these arguments should again be rejected.[15]

2. New Arguments

a. Plaintiff as a Sovereign and RICO Standing

Distributors raise another standing challenge that was not addressed in *Summit County*.[16] They assert that in seeking to vindicate sovereign interests, Plaintiff does not qualify as a "person" within the meaning of the RICO Act. They draw upon case law addressing a presumption that a sovereign is not considered a "person" in certain contexts, citing *Inyo County v. Paiute-Shoshone Indians of the Bishop Cmty. of the Bishop Colony*, 538 U.S. 701, 711 (2003).[17] (R. 924, PageID# 20991 & n.5; R. 1084, PageID# 27012-27013). Plaintiff responds that it does not seek recovery purely for its sovereign interests as *parens patriae* for injury to its economy, but also brings this action in its proprietary capacity for losses to its own property. (R. 731, ¶¶22, 291, 351; R. 1008 PageID# 24057-24059); *see Att'y Gen. of Canada v. R.J. Reynolds*

[15] The present action was instituted in the United States District Court for the Northern District of Oklahoma, within the Tenth Circuit, while the *Summit County* case originated in this District within the Sixth Circuit. To the extent there is any discrepancy in these Circuits' respective interpretation of federal law, "in a federal multidistrict litigation there is a preference for applying the law of the **transferee** district …." *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 912 (6th Cir. 2003) (emphasis added) (*citing In re Temporomandibular Joint (TMJ) Implants Prod. Liab. Litig.*, 97 F.3d 1050 (8th Cir. 1996); *Menowitz v. Brown*, 991 F.2d 36 (2d Cir. 1993)). "In an MDL proceeding, the transferee court applies the federal law of the circuit in which it is located…. Thus, **to the extent differences exist among jurisdictions, Sixth Circuit law controls**." *In re Vertrue Mktg. & Sales Practices Litig.*, 712 F. Supp. 2d 703, 712 (N.D. Ohio 2010) (Gaughan, J.) (emphasis added), *aff'd sub nom. In re Vertrue Inc. Mktg. & Sales Practices Litig.*, 719 F.3d 474 (6th Cir. 2013). Moreover, "[a]pplying divergent interpretations of the governing federal law to plaintiffs, depending solely upon where they initially filed suit, would surely reduce the efficiencies achievable through consolidated preparatory proceedings." *In re Korean Air Lines Disaster of Sept. 1, 1983*, 829 F.2d 1171, 1174 (D.C. Cir. 1987) (Ginsburg, J.) ("Indeed, because there is ultimately a single proper interpretation of federal law, the attempt to ascertain and apply diverse circuit interpretations simultaneously is inherently self-contradictory."), *aff'd sub nom. Chan v. Korean Air Lines*, Ltd., 490 U.S. 122, 109 S. Ct. 1676, 104 L. Ed. 2d 113 (1989).

[16] Distributors adopt arguments raised in Distributors' briefs submitted in support of their motion to dismiss the Blackfeet Nation's complaint (R. 924, R. 1084). (R. 925-1, PageID# 21028; R. 1086, PageID# 27070).

[17] *See also Vermont Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 780 (2000) (applying the "longstanding interpretive presumption that "person" does not include the sovereign" to conclude that a State is not a "person" subject to *qui tam* liability under the federal False Claims Act). (R. 924, PageID# 20911; R. 1084, PageID# 27012-27013).

Tobacco Holdings, Inc., 103 F. Supp. 2d 134, 149 (N.D.N.Y. 2000), *judgment aff'd*, 268 F.3d 103 (2d Cir. 2001) (holding that a foreign sovereign is a "person" for RICO purposes).

The *Inyo County* decision, relied upon by Distributors, explained that "qualification of a sovereign as a 'person'" may differ depending on the "legislative environment" in which the word appears, and it concluded that the plaintiff Tribe could not assert that it was immune from a state search warrant because it was not a person under 42 U.S.C. § 1983, a statute "designed to secure private rights against government encroachment." *Id.* at 711-712. In contrast, the word "person" within the "legislative environment" of the RICO Act is a term to be broadly and liberally construed to effectuate its remedial purposes.[18] The court concludes that as such, the word "person" within the meaning of Section 1964(c) includes Plaintiff who has alleged, as this court has previously described, "a wanton disregard for public health and safety exhibited by Defendants with respect to their legal duty to try to prevent the diversion of prescription opioids" thereby "flooding the legitimate medical market and creating a secondary 'black market' at great profit to Defendants and at great cost to Plaintiffs." (R. 1203, PageID# 29036-29037). The Defendants cite no case applying the presumption discussed in *Inyo* to a RICO claim. As the Summit County decisions recognize, asserting a cognizable RICO injury to "business or property" confers standing upon sovereign entities to maintain a civil claim under the Act. (R. 1025, PageID# 24818-24830; R. 1203, Page ID# 29036-29039); *see also Stillaguamish Tribe of Indians v. Nelson*, 2011 WL 13234272, at *7 (W.D. Wash. Jan. 28, 2011) (holding that the plaintiff Tribe is a "person" within the meaning of RICO because it "does not seek to vindicate its sovereign rights, but rather seeks to assert a right that RICO makes available to every

[18] Plaintiff notes that the principal sponsor of the RICO bill specifically recognized, as one of "two examples of types of problems RICO was designed to address . . . the illicit prescription drug industry." *United States v. Turkette*, 452 U.S. 576 at 590 (1981) (citing 116 Cong. Rec. 592 (1970)). (R. 1008, PageID# 24050).

'person,' the right to recover damages caused by an injury to business or property," distinguishing *Inyo*). Accordingly, Distributors' argument to the contrary is not well taken.

b. Causation

All Defendants contend that Plaintiff's RICO claims and all others raised in the FAC fail sufficiently to plead proximate causation.[19] The parties agree that *Holmes v. Sec. Inv'r Prot. Corp.*, 503 U.S. 258, 268 (1992) provides the analytical framework for determining whether Defendants may be held responsible for the injuries that Plaintiff alleges are attributable to their misconduct. *Holmes* set forth the following three factors as relevant to determining whether an alleged causal link is so attenuated as to bar recovery: (1) the difficulty of ascertaining what damages are attributable to the alleged conduct rather than other factors; (2) the possibility of forcing the court to adopt complicated apportionment rules to avoid the risk of multiple recoveries by plaintiffs asserting different levels of injury; and (3) whether the "general interest in deterring injurious conduct" is served by suits brought by directly injured victims, therefore avoiding the need to "grapple" with the first two problems that attend actions of more remotely injured plaintiffs. 503 U.S. at 268-270.

[19] All the defendant groups challenge causation, some by briefing in this case and some by reference to all or certain portions of briefs submitted in this case and/or other cases. Manufacturers' brief addresses every element of causation. Distributors' RICO arguments in the Tribes' actions address the sufficiency of the predicate acts allegations. Their Joint Muscogee Briefs (R. 925-1, PageID# 21038-21030; R. 1086, PageID# 27070-27071) refer to their Joint Blackfeet Briefs (R. 924, PageID# 20986-20996), which in turn refers to their Joint Summit Brief (R. 491-1, § 1.B). Similarly, the Pharmacies' RICO argument is very brief, addressing only a failure to satisfy Rule 9(b) and group pleading. (R. 928-1, PageID# 21105-21106; R. 1087, PageID# 27160-27162). They cite generally to arguments in both the Manufactures' and Distributors' Summit briefs (moving and reply) as "applying with equal force to any RICO claim" against the Pharmacies – without further elaboration – and also cite to the Pharmacies' Broward County Briefs (R. 582-1, pp. 3-5; R. 825, pp. 3-5) which assert arguments to those raised in this action and are supported by Florida case law. The Generic Manufacturers focus on the absence of allegations pertaining to them specifically; and, as to RICO allege that no predicate act supports the 'failure to prevent diversion' theory (specifically referring to the CSA violations), and refer to Manufacturers' Joint Briefs in this and the Summit actions challenging the alleged RICO injury and causation. R. 929-1, PageID# 21249-21250; R. 1090, PageID# 27390-27391).

Analyzing similar causation arguments applied to an analogous set of facts, this court in *Summit County* concluded that the relationship between the plaintiffs' injuries and the defendants' conduct was less remote than the Sixth Circuit found sufficient in *Trollinger v. Tyson Foods, Inc.*, 370 F.3d 602, 618-619 (6th Cir. 2004) (refusing to determine whether the alleged "multi-link chain of causation" satisfied proximate cause requirements at the pleading stage, as "many fact-driven question[s]" were presented). (R. 1203, PageID# 29027-29029). The court need not reiterate the extensive analysis from *Summit County*, and finds the same conclusion applies here for the same reasons. Therein, the court determined:

> Plaintiffs' alleged damages are not speculative, but concrete and ascertainable. No other party can vindicate the law and deter Defendants' alleged conduct because Plaintiffs' asserted damages are not recoverable by any other party. Finally, there is no potential for—and thus no reason for the Court to have to adopt complicated rules to prevent—duplicative recoveries. As none of the *Holmes* concerns are implicated in this case, the Court finds that Plaintiffs have sufficiently alleged proximate cause for their RICO claims.

(R. 1203, PageID# 29029).

For the reasons stated herein, as well as in *Summit County*, the court finds that, at the pleading stage, Plaintiff has plausibly alleged that its claimed injuries were proximately caused by Defendants' alleged conduct.

c. Fed. R. Civ. P. 9(b) and Group Pleading

1. Fraud pleading

All Defendants challenge Plaintiff's RICO pleading as failing to satisfy Fed. R. Civ. P. 9(b)'s particularity requirement.[20] As noted above, the allegations in the FAC and the arguments raised in the parties' memoranda are substantially similar to those in *Summit County*, and the

[20] Manufacturers (R. 933-1, PageID# 21261-21269; R. 1089, PageID# 27251-27252); Distributors (R. 924, PageID# 20991-20994; R. 1084, 27017-27018; R. 925-1, PageID# 21030); Pharmacies (R. 928-1, 21105-21106; R 1087, PageID# 27155-27158); Generic Manufacturers (R. 922-1, PageID# 21135-21139; R. 1090, 27387-27390).

arguments asserted in support of and in opposition to dismissal. Accordingly, the court's analysis in *Summit County* (R. 1025, PageID# 24845-24850 and R. 1203), applies here and leads to the same conclusion, *i.e.*, that Plaintiff's allegations are sufficiently detailed to provide fair notice to each of the Defendants of the nature of the claims against them and therefor complies with the level of specificity required by Rule 9(b). *See Williams v. Duke Energy Int'l, Inc.*, 681 F.3d 788, 803 (6th Cir. 2012).

2. Group pleading

Defendants also challenge the propriety of what they characterize as "group pleading."[21] However, the FAC provides fair notice of the claims sufficient to permit the Defendants to understand and respond to them. The decisions from this Circuit relied upon by the Defendants that reject group pleading, do so only where the complaint at issue fails to provide fair notice.[22] Those decisions do not stand for the proposition that where multiple defendants are alleged to have engaged the same pattern of conduct or conspired in a fraudulent scheme, that a plaintiff must reiterate its allegations against each defendant individually. Such a finding would

[21] Manufacturers (R. 933-1, PageID# 21265-21266; R. 1089, PageID# 27247, 27250, 27251); Distributors (R. 924, PageID# 20992-20993, 21009; R. 1084, PageID# 27009, 27017 n.8); Pharmacies (R. 928-1, PageID# 21102; R. 1087, PageID# 27154-27155, 27161); Generic Manufacturers (R. 929-1, PageID# 21138-21139; R. 1090, PageID# 27390-27392).

[22] *E.g., Kurek v. Ohio Dept. of Develop. Disabilities*, 2017 WL 1555930, *6 (N.D. Ohio Jan. 20, 2017) (finding pleading insufficient where plaintiff suing former employer, unions, and former co-workers for denial of due process rights "fails, as she has throughout her complaint, to attribute such denial to specific acts by any particular State defendants that contravened due process"); *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 932 (6th Cir. 2014) (finding that the complaint failed to provide fair notice where '[i]t asserts without elaboration Plaintiffs' belief that the Generic Manufacturers failed to update their warnings, providing no factual basis for that belief"); *Marie v. Am. Red. Cross*, 771 F.3d 344, 364 (6th Cir. 2014) (affirming dismissal of *Bivens* claim where the complaint omitted any reference to *Bivens*, commenting that any intent to assert it could not have been "less clear"); *Cataldo v. U.S. Steel Corp.*, 676 F.3d 542, 551 (6th Cir. 2012) (finding pleading fell "well short" of Rule 9(b) requirements where it was alleged that "[n]umerous plaintiffs" asked vaguely-referred-to "defendants" for assurances and received "promises" and "false, inaccurate or misleading information" regarding employee benefits); *Hoover v. Langston Equip. Assocs., Inc.*, 958 F.2d 742, 745 (6th Cir. 1992) (finding "[t]he complaint does not enable a particular defendant to determine with what it is charged" where "plaintiffs had articulated general averments of fraud attributed to 'the defendants,'" and "identifie[d] relationships between various of the defendants but it allege[d] misrepresentations without sufficiently identifying which defendants made them").

exponentially increase the length of pleadings while adding no substantive value. As the Sixth Circuit has observed, "the most that can be said is that 'particular' allegations of fraud may demand different things in different contexts." *Walgreen,* 846 F.3d at 881.

Here, Plaintiff alleges that each of the groups it identifies share common regulatory and legal obligations and have breached their respective duties by undertaking the same variety of misconduct. The Manufacturing Defendants are alleged to have devised, operated, and concealed a multi-faceted fraudulent marketing scheme that intended to and did influence the prescribing habits of doctors and the public's perception of opioids, resulting in a massive increase in prescriptions, use, and diversion of drugs and a consequential profit increase for those in the manufacturing and distribution chain. (*e.g.*, ¶¶1-10). The Defendants that are engaged in distribution and dispensing activities are alleged to have contributed essentially to the scheme by failing to abide by anti-diversion obligations and concealing that failure (*e.g.*, ¶¶11-16). As registrants under the CSA, all Defendants are alleged to have anti-diversion obligations, and all are alleged to have violated those duties. (*e.g.*, ¶¶166-177, 331-336).

The Pharmacies' contention—that the allegations pertain only to Manufacturers and Distributors—ignores Plaintiff's allegations pertaining to their complained-of misconduct and its consequences (*e.g.,* R. 731, ¶¶ 14, 20); the duties imposed on the Pharmacy Defendants, which are also alleged against Diversion Defendants, by federal and state laws and regulations (*e.g.,* ¶¶ 98, 162-199); their alleged failure to comply with those obligations (*e.g.*, ¶¶ 237-244); and the consequences of that alleged misconduct. (*e.g.,* ¶¶ 20, 285-293). The FAC adequately alleges conduct that, if proven, may subject the Pharmacy Defendants to RICO liability as members of the Opioid Supply Chain Enterprise (Count II) (¶¶ 329-352, 380-408) as well as to liability under the other claims asserted by Plaintiff. The Pharmacies also argue that claims characterizing

"some (though not all)" of them as "Distribution Defendants" should "be dismissed under *Iqbal.*" (R. 928-1, PageID# 21102; R. 1087, PageID# 27154-27155). The court notes, however, that the entities identified in the FAC as both Pharmacies and Distributors are alleged to have engaged in both distribution and dispensing of prescription opioids. (*see* ¶¶50-52, 66-68).

The Generic Manufacturers assert that the FAC alleges no misconduct on their part because they do not engage in promotion of their product, a factual assertion more appropriately addressed upon a full record. (R. 929-1, 21138-21139; R. 1090, PageID# 27387-27388, 27390-27392). Even if the evidence confirms the veracity of the contention that the Generic Manufacturers did not directly promote their generic opioid medications, the FAC nevertheless alleges other misconduct on their part. For example, Plaintiff claims that as Marketing Manufacturer Defendants they participated in and supported a fraudulent scheme by funding, contributing content, and controlling the KOLs and front groups (*e.g.,* R. 731, ¶¶104-105, 127, 130), by engaging in an association-in-fact with those persons and entities to effectuate its common purpose of increasing profits by expanding the opioid market (*e.g.*, ¶¶296-299, 230, 304-312, 316), and that "rather than act in accordance with their duties, Generic Marketing Manufacturer Defendants aggressively marketed their generic opioid products to drug distributors, prescription benefit managers, formularies, insurance companies, and other third parties to increase their own market share among generics." (¶¶160-161). As to the Generic Manufacturers' argument that the FAC improperly "lumps" KVK and API with Distributors and Pharmacy Defendants, the court notes that those two entities are alleged to both manufacture and distribute prescription opioids. (¶¶ 38, 39, 41, 42).

The Defendants have not met their burden to demonstrate that the FAC fails to give them fair notice of Plaintiff's claims against each of them or the grounds upon which they rest.

D. Manufacturers' Preemption Arguments

Manufacturers seek dismissal of Plaintiff's state law claims on preemption grounds, and re-characterize the claims as seeking to "impose liability for the Manufacturers' marketing of opioids (1) for the treatment of chronic pain, and (2) without limitation on dosages or duration of treatment." (R. 1089, PageID# 27246; see also R. 933-1, PageID# 21256).[23] They also argue that "any surviving claims premised on alleged marketing misrepresentations are preempted to the extent the relevant representations are ones a pharmaceutical manufacturer could not alter without violating federal law."[24] (R. 933-1, PageID# 21256). Plaintiff disputes this characterization of their claims, and insists that they are premised on, among other things, allegations that the Brand-Name Manufacturers 1) misrepresented the risks of addiction to prescription opioids, 2) misleadingly claimed that patients who were showing signs of addiction were not actually addicted, and 3) falsely claimed that there was no risk in increasing opioid dosages to treat chronic pain. (R. 1008, PageID# 23956).[25]

The court does not interpret the FAC claims as narrowly as Brand-Name Manufacturers. At this stage, the court must construe the factual allegations in the light most favorable to Plaintiff and accept well-plead allegations as true. *See* sect. I, *supra*. Plaintiff's state law claims are based on allegations asserting, for example, misrepresentations concerning the risks of addiction, the risks of increasing dosages and representations concerning pseudoaddiction.

---

[23] Manufacturers point to several particular allegations in the Complaint that refer to these assertedly preempted bases of liability. *See* R. 933-1, PageID# 21258-59, n. 13, 14.

[24] In a footnote, the Brand-Name Manufacturers incorporate by reference arguments relating to the preemption of claims based on off-label uses (*i.e.* uses beyond those approved by FDA) from their *Summit County* Motion to Dismiss. (R. 933-1, PageID# 21259 n. 15) For the reasons articulated in the Report and Recommendation in the *Summit County* case, the Court finds that those claims are not preempted. (R. 1203, pp. 50-51).

[25] Manufacturers also argue that Plaintiff "effectively concedes that Manufacturers cannot be liable for simply representing that opioids can be safe and effective for the treatment of chronic, non-cancer pain." (R. 1089, PageID# 27243. The Court does not construe Plaintiff's brief as offering such a concession. However, after discovery, Plaintiff may narrow its claims and Manufacturers may renew their arguments upon a full record.

Therefore, consistent with the opinion in *Summit County*, the court denies Manufacturers' maximal claim, that Plaintiff's state law claims are "generally preempted." (R. 1025, PageID# 24854-56, pp. 48-50).[26]

Manufacturers, however, assert a new basis for preemption that was not briefed in *Summit County*. They rely upon an FDA letter responding to a July 2012 citizen petition from a group known as Physicians for Responsible Opioid Prescribing (the "PROP Petition"), which Plaintiff cited in its FAC**.** (R. 731, PageID # 17106, n.32). The PROP petition raised concerns "about the safety and efficacy of opioid analgesic drugs for long-term use in chronic non-cancer pain" (R. 933-3, PageID# 21310), requested that the FDA specify maximum daily dosages and durations of treatment for certain opioids (*Id.*), and also requested that the FDA distinguish between cancer and non-cancer pain in approving labeling. (R. 933-3, PageID# 21318). The FDA granted the petition in part and denied it in part. It also determined that "important safety labeling changes are needed to the labeling of ER/LA opioid analgesics." *Id.* at 21310. Manufacturers, however, focus on language such as the FDA indicating it knew of "no physiological or pharmacological basis upon which to differentiate the treatment of chronic pain in a cancer setting or patient from the treatment of chronic pain in the absence of cancer." *Id.* It also declined "to make a distinction between cancer and non-cancer pain in opioid labeling." *Id*. at 21318. The FDA further declined "to specify a maximum daily dose or duration of use for opioids at this time." *Id.* at 21320. The FDA's response, however, noted significant risks associated with opioid use; it ordered certain opioid drug sponsors "to conduct postapproval

[26] While the FAC is not devoid of allegations relating to the risks attending increased opioid dosage or duration, those allegations, with minor exceptions do not focus on any maximum dosage or duration of use. *See*, *e.g. id.* at ¶ 121: alleging that Defendants' marketing materials stated "opioids have no 'ceiling dose.'" Rather, they are included to form the basis of claims that various defendants misrepresented the risks of addiction at increasing dosages or durations of use. The court does not agree that liability for alleged statements about the risks of increased dosages would be tantamount to a requirement imposing limits on dosage or duration.

studies and clinical trials . . . to assess certain known serious risks of ER/LA opioid use . . .” (*Id*. at 21310-11); and it stated that it “declines to specify or recommend a maximum daily dose or duration of use for any opioid at this time . . . However, FDA has determined that PMRs [post-marketing requirements] are necessary to . . . address, among other things, the effect of dose and duration of opioid use on these serious risks.” (*Id*. at 21320).

Manufacturers correctly point out that representations made in marketing materials are considered “labeling” for purposes of the FDA, and note that such advertising and marketing materials “must be consistent with the specific pre-approved label submitted to the FDA.” (R. 1089, PageID# 27243-44). They further assert that “[a]ny state law claim that seeks to impose liability on the Manufacturers for failing to include statements on any of their advertising regarding the correct dosage or duration of opioid treatment – or otherwise make statements inconsistent with an opioid medication’s FDA-approved uses – is preempted.” (R. 1089, PageID# 27244).

The Supreme Court in *Wyeth v. Levine* explained that in enacting the FDCA without an express preemption provision, Congress expressed an intention that FDA enforcement and oversight should not be the sole mechanism for ensuring the safety and efficacy of drugs. 555 U.S. 555 at 574. The Court noted as follows:

> In keeping with Congress’ decision not to preempt common law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.. . . Thus, the FDA long maintained that state law offers an addition, and important, layer of consumer protection that complements FDA regulation.

Id. at 578. Federal preemption principles can arise when state law, through a tort action alleging insufficient labeling, seeks to impose upon a manufacturer a duty to warn beyond what the FDA would approve. In such a case, because it would be impossible for the manufacturer to comply with both state and federal requirements, the state requirement is preempted. Manufacturers correctly assert that a "brand-name manufacturer that markets its product with FDA-approved warnings cannot be held liable under state law for failing to issue different warnings if the FDA would have rejected those different warnings." *Wyeth v. Levine*, 555 U.S. 555, 571 (2009) ("absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."); *also Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1098 (10th Cir. 2017) (a state tort claim is preempted if a pharmaceutical company presents clear evidence that the FDA would have rejected an effort to strengthen the label's warnings."). Moreover, the Court established that "absent clear evidence that the FDA would not have approved a [requested change in labelling], we will not conclude that it was impossible for [a manufacturer] to comply with both federal and state requirements." *Wyeth,* 555 U.S. at 571.

The Seventh Circuit Court of Appeals concisely described the legal and regulatory background that informs this preemption analysis.

> The journey to deciphering the "clear evidence" standard begins with understanding how drug manufacturers receive approval to market new prescription drugs and to change a label once it has been approved. Before marketing a new drug, the manufacturer must submit a New Drug Application to the FDA, which demonstrates by "substantial evidence" that the medication is efficacious. 21 U.S.C. 355(d)(5). The FDA's approval is then conditioned on the manufacturer's use of the label it suggests. 21 C.F.R. § 314.105(b). Even after the medication is approved, the FDA continues to have authority over it and its label. 21 C.F.R. 314.80–.81. The manufacturer, however, has the ability to change the label without FDA approval through a "changes being effected" (CBE) labeling change. The CBE regulation allows a manufacturer to modify a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add

> or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product" and to do so when it files its supplemental application, before the FDA has the opportunity to consider whether or not it will accept the change. 21 C.F.R. § 314.70(c)(6)(iii)(A), (C). The ability to make CBE labeling changes underscores a central premise of federal drug regulation: A "manufacturer bears responsibility for the content of its label at all times." *Levine*, 129 S.Ct. at 1197–98. While it is important for a manufacturer to warn of potential side effects, it is equally important that it not overwarn because overwarning can deter potentially beneficial uses of the drug by making it seem riskier than warranted and can dilute the effectiveness of valid warnings. Therefore, warnings may only be added when there is "reasonable evidence of an association of a serious hazard with the drug." 21 C.F.R. § 201.57(e)(2003). It is technically a violation of federal law to propose a CBE that is not based on reasonable evidence. 18 U.S.C. § 1001.

Mason v. SmithKline Beecham Corp., 596 F.3d 387, 391-392 (7th Cir. 2010).

Plaintiff argues "[e]ven if the [Muscogee] Nation sought to hold Brand-Name Manufacturers liable for not giving new warnings, rather than for misrepresenting the benefits and risks of opioid use, Brand-Manufacturers have not met, and cannot even begin to meet, their burden, on their motion to dismiss, to show that the FDA would not approve the new warnings the Nation hypothetically seek." (R. 1008, PageID# 23957). Moreover, whether there exists clear evidence that the FDA would reject a certain warning is, as Plaintiff's argue, a question of fact that cannot be resolved on a motion to dismiss. (R. 1008, PageID# 23957-59). It cites *In re Fosamax*, 852 F.3d 268 (3d. Cir. 2017), in which the Third Circuit Court of Appeals stated: "We therefore conclude that the question of whether the FDA would have approved a plaintiff's proposed warning is a question of fact for the jury. A state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change." *Id.* at 293.[27] Other cases are not nearly so explicit on the issue, but nevertheless point to the fact-sensitive nature of the "clear evidence" inquiry. *See Cerveny v. Aventis, Inc.*, 855 F.3d

[27] The decision is currently on appeal before the United States Supreme Court. *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig.*, 852 F.3d 268, 272 (3d Cir. 2017), *cert. granted sub nom. Merck Sharp & Dohme Corp v. Albrecht*, 138 S. Ct. 2705, 201 L. Ed. 2d 1095 (2018).

1091, 1099 (10th Cir. 2017) (declining to answer the question because it was not raised in the parties' briefs, but nevertheless affirming a grant of defendant's motion for summary judgment based on preemption after a review of the regulatory history and a prior FDA opinion in response to a citizen petition.); *Mason*, 596 F.3d at 396 (rejecting preemption on review of grant of motion for summary judgment; noting "extensive showing required by *Levine"*).

Manufacturers contend that the FDA's PROP letter provides, as a matter of law, just such "clear evidence" that the FDA would reject any labeling change prohibiting the promotion of opioids for chronic, non-cancer pain or requiring that manufacturers include warnings concerning maximum dosage and duration of treatment. As such, they present the letter as conclusive evidence that it would be impossible for them to comply with federal law as well as state law that required them to make such changes in their labeling. As a result, they insist that Plaintiff's state law claims are preempted to the extent that they seek to impose liability for failing to make such changes. (R. 1089, PageID# 27244-45). However, their briefing does not respond squarely to the *Fosamax* ruling and argues that *Cerveny* rejected the argument that "denial of a citizen petition, by itself, cannot constitute clear evidence." 855 F.3d at 1103; (R. 1089, PageID# 27244).[28] Indeed, case law demonstrates that an FDA rejection of a warning can satisfy the "clear evidence" standard, but Defendants have not identified any caselaw that mandates a finding that the PROP petition, in this instance, furnishes such clear evidence here. Plaintiff's FAC, unlike the above-referenced PROP Petition, does not propose specific labeling

[28] They also cite *Robinson v. McNeil Consumer Healthcare*, 615 F.3d 861 (7th Cir. 2010) in which the court affirmed the district court's refusal to amend a final pretrial order to include a breach of implied warranty claim, noting that the claim was unlikely to succeed because of the clear evidence standard under *Wyeth.* The court stated that the "clear evidence" was "the agency's refusal to require a reference to SJS/TEN on the label of over-the-counter drugs containing ibuprofen, when it had been asked to do so in the submission to which the agency was responding. And it would be odd to think that McNeil had a legal duty to guarantee against a risk that the FDA thought not worth warning against." *Id.* at 873. The *Robinson* decision is instructive, but preemption was not an issue squarely before the court. *See In re Testosterone Replacement Therapy*, 2017 WL 1836435, at *10.

changes that can be readily considered in connection with the FDA response. Without contextual evidence and pertinent expert reports, the court would be ruling in a vacuum. The court concludes that the significance to this case, and perhaps the MDL, of the PROP petition and FDA response, create substantial questions of fact that cannot be resolved on the limited record before the court.

Furthermore, Manufacturers have not shown that Plaintiff's claims—based on alleged misrepresentations about the risks of addiction to opioids, about pseudoaddiction, or about the risks of increasing opioid dosages to treat chronic pain—would impose state law requirements that would render it impossible for Manufacturers to comply with federal law requirements or pose an obstacle to the accomplishment of the FDA's Congressionally-mandated purposes under *Wyeth's* "clear evidence" standard. In *Summit County*, this court concluded that the plaintiffs' state law claims similarly based on Manufacturers' marketing representations were not preempted. (R. 1025, PageID# 24854-56, pp. 48-50). Consequently, at this current stage of the proceedings, the Brand-Name Manufacturers have not met their burden to show that Plaintiff's claims are preempted.

E. Generic Manufacturers' Preemption Arguments

The Generic Manufacturers argue that Plaintiff's state law claims are impliedly preempted by federal law under a theory of impossibility preemption. They construe the state law claims as "based on the Generic Manufacturers' product labels and alleged failure to provide additional warnings" (R. 929, PageID# 21139-40) and argue that these claims are preempted because it would be impossible to comply with the supposed tort duty Plaintiff alleges while also adhering to federal law, namely the Food, Drug and Cosmetic Act and its regulations.

The allegations that are the focus of the Generic Manufacturers' preemption argument are accurately described in their briefing, but those are not the only allegations upon which Plaintiff's state law claims rest. The FAC also alleges Generic Manufacturers failed to prevent diversion (R. 731 at ¶ 468) and misrepresented and minimized the risks of opioid addiction. (R. 731 at ¶ 102-137).[29] The following analysis of the parties' preemption arguments is limited to the allegations concerning the Generic Manufacturers' failure to provide additional warnings to correct or clarify the alleged misrepresentations of the Brand-Name Manufacturers.

The FDCA imposes rigorous requirements on manufacturers seeking federal approval of a new drug to "prove that it is safe and effective and that the proposed label is accurate and adequate." *PLIVA v. Mensing*, 564 U.S. 604, 612 (2011). The Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Amendments to the FDCA, enables generic drugs to obtain FDA approval by showing equivalence to a drug already approved by the FDA. *Id.* The FDCA requires generic medications to be the same as their branded equivalent in every clinically significant way, including with respect to labeling. Courts refer to this as the "sameness" requirement. Under the sameness principle, the generic manufacturer must also "show that the [safety and efficacy] labeling proposed . . . is the same as

[29] The Generic Manufacturers assert that their business model dictates that they engage in no advertising or marketing activities. (R. 929, PageID# 21132). However plausible this assertion may be, the FAC nevertheless includes allegations the Marketing Manufacturer Defendants, a pleading category that includes the Generic Manufacturers, have engaged in similar acts of aggressive and misleading marketing. Moreover, some of the Generic Manufacturers or their corporate affiliates are also alleged to sell name-brand prescription opioids. Only Amneal and KVK are alleged to sell only generic opioids. The Generic Manufacturers make no effort in their briefing to distinguish between those that sell only generics and those that sell branded opioids and no effort to distinguish, within one corporate family, between those subsidiaries or divisions that sell branded opioids and those that sell generics. Instead, they move the court to dismiss all the state law claims against all the Generic Manufacturers, including the ones that also sell brand-name opioids. Given the nature of this MDL, such aggregative briefing is not inappropriate. The Generic Manufacturers will have the opportunity to individuate and clarify their status and what activities they have engaged in as discovery progresses. At this phase of the litigation, however, the court accepts Plaintiff's allegations as true.

the labeling approved for the [brand-name] drug." *Id.* at 612-13 (citing 21 U.S.C. § 355(j)(2)(A)(v)).

Under the FDCA and its regulations, the term "labeling" refers to "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). "The Supreme Court has held that the first clause 'clearly embraces advertising or descriptive matter that goes with the package in which the articles are transported.'" *Strayhorn v. Wyeth Pharmaceuticals*, 737 F.3d 378, 394 (6th Cir. 2013) (quoting *Kordel v. United States*, 335 U.S. 345, 349–50, 69 (1948)). "With respect to the second clause, '[o]ne article or thing is accompanied by another when it supplements or explains it.... No physical attachment one to the other is necessary.'" *Strayhorn*, 737 F.3d at 394 (quoting *Korbdel*, 335 U.S. at 349-50). Labeling also includes "[b]rochures, booklets, mailing pieces, detailing pieces, file cards, bulletins, calendars, price lists, catalogs, house organs, letters, motion picture films, film strips, lantern slides, sound recordings, exhibits, literature, and reprints" and "similar pieces of printed, audio, or visual matter descriptive of a drug . . . for use by medical practitioners, pharmacists, or nurses, containing drug information supplied by the manufacturer." 21 C.F.R. § 202.1(l)(2). "Such labeling must be consistent with the drug's approved labeling." *Strayhorn*, 737 F.3d at 394 (citing 21 C.F.R. § 201.100(d)(1); 21 C.F.R. § 202.1(e)(4)). Furthermore, the Supreme Court "has explicitly held that 'Dear Doctor' letters also qualify as labeling for purposes of the FDCA." *In re Lipitor*, 185 F.Supp.3d 761, 772 (D.S.C. 2016) (citing *Mensing,* 564 U.S. at 615).

To support their argument for preemption, the Generic Manufacturers cite *Mensing*, in which the Supreme Court held that a state law claim that would require additional or different warnings was preempted by the FDCA. The plaintiff brought a product liability claim to recover

damages for serious neurological side-effects after taking metoclopramide, a generic version of Reglan, a drug that treats esophageal reflux. The plaintiff argued that the generic manufacturer knew or should have known that the drug's label did not adequately warn of the side effects, and tortiously failed to provide adequate warning labels. The Court concluded that a ruling in the plaintiff's favor would require the generic manufacturer to use a label that was stronger than the one approved by the FDA and used by the brand-name manufacturer. *Id.* at 617-18. The Court ruled that, because the sameness principle required generic manufacturers to maintain the same labeling as the branded drug, the state law claim was preempted as it would have been impossible for the generic manufacturer to comply with both state tort law to change its label and the FDA requirement that its labeling be the same as the branded drug. *Id.; see also Mutual Pharmaceutical Co., v. Bartlett*, 570 U.S. 472 (2013) (state law claims preempted because they required generic manufacturer to strengthen warnings on label).

Moreover, in *Strayhorn*, as in *Mensing*, plaintiffs alleged that the generic manufacturer of Reglan "knew or should have known that most physicians did not know or fully appreciate the seriousness of the risks associated with Reglan. . . . Thus, all Defendants should have known that the Physician's Desk Reference monograph for Reglan and the package inserts for Reglan and metoclopramide were deficient, inaccurate, [or] false and misleading in communicating [information] to the medical community in general, to physicians, or to the public. Plaintiffs allege that all Defendants failed to adequately inform physicians and misled [them] about the risks associated with their metoclopramide drug products." 737 F.3d at 385. The Sixth Circuit rejected the plaintiffs' argument that under *Mensing*, "only claims based on the adequacy of the information on the drug's label are preempted, not claims based on a manufacturer's duty to provide a warning beyond the label." *Id.* at 391. The court also rejected plaintiffs' argument that

the generic manufacturers, "on their own initiative, could have distributed ... Dear Doctor letters to medical professionals to warn them of the dangers of metoclopramide that were not adequately communicated on the drug's label." *Id.* The court reasoned that these claims must be preempted because they are, "at their core, claims that the generic manufacturer failed to provide additional warnings beyond that which was required by federal law of brand-name manufacturers." *Id.*

The Generic Manufacturers argue that Plaintiff's state law claims, like those in *Strayhorn*, *Mensing*, and *Bartlett*, rest on allegations that they should have provided information that went beyond the FDA-approved labeling provided by the name-brand manufacturers. They argue that those claims are preempted because it would be impossible for the Generic Manufacturers to comply with the supposed state law duty without running afoul of the federal sameness requirement. (R. 929-1, PageID# 21146-47).

Plaintiff argues that the Generic Manufacturers are mischaracterizing their claims to support their preemption argument, and insist that it "does not assert that the Generic Manufacturers should have provided label warnings different from those required by the FDA." (R. 1008, PageID # 23959). The allegations that form the basis of Plaintiff's allegations specific to the Generic Manufacturers must be understood in relationship to its allegations concerning the Brand-Name Manufacturers. Having alleged that the Brand-Name Manufacturers misled the public by making allegedly false representations concerning safety, suitability, and addiction, Plaintiff asserts that the Generic Manufacturers had a state law duty of care to "counter [those] misstatements and misrepresentations ... so as to ensure that the FDA-approved label information and warnings were effectively communicated to physicians and patients, and not undermined by"

the allegedly false statements of the Brand-Name Manufacturers. (R. 1008, PageID# 23955-56). The allegation on which the preemption inquiry rests reads as follows:

> Generic Marketing Manufacturer Defendants also failed to timely and effectively correct misstatements and misrepresentations made by name-brand opioid manufacturers such as Purdue, Endo, and others. Their failure to do so constituted a breach of duty to purchasers and consumers of their products. Specifically, they failed to ensure that the warning language and other information was effectively communicated to physicians and patients – including **by means of communication that did not require language different from the approved FDA label**, and did not require permission or assistance from the FDA, such as sending doctors and healthcare providers **letters that did not contain additional or substantial new warning information, but which highlighted and explained the products' warnings, labeling, and other information**. Such letters can be appropriate to convey "important safety concern[s]," such as "clinically important new information about a known adverse reaction.

R. 731 at ¶ 158 (emphasis added).

Plaintiff thus claims that it is not asserting that the Generic Manufacturers should have provided warnings different from those required by the FDA, but is actually alleging that the Generic Manufacturers "failed to ensure that the warning language...was effectively communicated to physicians and patients, including by means of communication that did not require language different from" that approved by the FDA. Such explanations, Plaintiff posits, could have come in the form of letters to doctors and other healthcare providers that "highlighted and explained the [FDA-approved] products' warnings, labeling, and other information." (R. 1008, PageID# 23959).

Plaintiff argues that claims based on these allegations are not preempted, citing *Fulgenzi v. Pliva, Inc.*, 711 F.3d 578 (6th Cir. 2013). In *Fulgenzi*, the defendant had failed to update the labeling on its generic Reglan for some years after the FDA had mandated an enhanced warning, during which time the plaintiff used the drug and suffered serious side-effects. The Sixth Circuit addressed the question of whether the generic labeling was inadequate to the extent that it did not

include the language contained in the FDA-approved update. The court concluded that the claim was not preempted because requiring the generic manufacturer to update its label to conform to the FDA-approved brand-name label would not offend the sameness principle. 711 F.3d 578, 584. The court clarified that "Fulgenzi's claims survive [preemption] only to the extent PLIVA's actions were permitted by federal law." *Id.*

Plaintiff maintains that its claims similarly do not run afoul of the sameness principle, arguing that if "federal law did not preempt Fulgenzi's claim that PLIVA was liable for failing to communicate – adequately and effectively – the updated FDA-approved warning (without changing its labeling), it follows that federal law does not preempt Plaintiff's claims that Generic Manufacturers are liable for failing to communicate effectively and adequately to physicians and patients, through "Dear Doctor" letters or other communications, the *current* FDA-approved warning." *See also, Teva Pharmaceuticals v. Superior Court of Orange County*, 217 Cal.App.4th 96 (2013) (adopting the *Fulgenzi* analysis under similar facts). (R. 1008, PageID# 23959-60).

The Generic Manufacturers' Reply stresses language in *In re Darvocet, Darvon, and Propoxyphen Products Liability*, 756 F.3d 917 (2014). The plaintiff in *Darvocet* brought a series of state law claims founded on allegations that the generic manufacturers should have sent "Dear Doctor" letters to healthcare providers regarding the risks of propoxyphene. The Sixth Circuit held those claims to be preempted, reasoning that:

> [i]n *Mensing*, the Supreme Court held that generic manufacturers cannot send "Dear Doctor" Letters unless their brand counterparts do so first because "if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly misleading." *Mensing*, 564 U.S. 604, 615. In other words, generic manufacturers cannot violate the duty of sameness. The only two federal appellate courts to consider this issue have rejected "failure-to-communicate" claims similar to those Plaintiffs advance. *Morris v. PLIVA*, 713 F.3d 774, 777 (5th Cir. 2013) ("Under federal law, the inquiry is whether the brand-name manufacturers sent out a warning, not whether

> the proposed warning to be disseminated contains substantially similar information as the label. Because no brand-name manufacturer sent a warning ... the generic manufacturers were not at liberty to do so."); *Guarino v. Wyeth*, LLC, 719 F.3d 1245, 1249 (11th Cir. 2013) ("Because the duty of sameness prohibits the generic manufacturers from taking such actions unilaterally, they are dependent on brand-names taking the lead. That fact is determinative here. We reject the failure-to-communicate theory of liability, as it is preempted by federal law.")

756 F.3d at 932-33.

The cases the Generic Manufacturers cite present a consistent jurisprudence of preemption of state law claims based on inadequate labeling of generic drugs. But, as such, they are not precisely analogous to the situation before the court, for Plaintiff claims that it does not seek an enhancement of the Generic Manufacturers' labeling. Rather, it asserts that it merely seeks to hold the Generic Manufacturers liable for failing to explain or correct the Brand-Name Manufacturers' allegedly false marketing, communications which are not FDA-approved. The Court does not agree with this characterization of the allegations in question.

Darvocet and the cases cited therein – *Mensing, Morris, and Guarino* – speak clearly on the preemption of claims based on a so-called "failure to warn" theory, and apply to the allegations presently under consideration. Those cases involved situations in which brand-name manufacturers were silent about certain risks of the drugs they sold. The courts refused to place the generic manufacturer in the lead, ahead of brand-name manufacturers in disseminating warnings about newly understood risks. They stressed that generic manufacturers "were not at liberty" to send a warning where the brand-names had not done so. *Morris v. PLIVA*, 713 F.3d 774, 777 (5th Cir. 2013). The *Mensing* decision concluded: "State tort law places a duty directly on all drug manufacturers to adequately and safely label their products. Taking Mensing and Demahy's allegations as true, this duty required the [generic] Manufacturers to use a different, stronger label than the label they actually used. Federal drug regulations, as interpreted by the

FDA, prevented the Manufacturers from independently changing their generic drugs' safety labels." 564 U.S. 604 at 617.

Although Plaintiff argues that the Generic Manufacturers can correct the Brand-Name Manufacturers' alleged misrepresentations without violating the sameness principle, they seek to impose upon the Generic Manufacturers liability for not sending warnings that the Brand-Name Manufacturers had not sent. Although such action may have altered the course of events leading to this MDL, for the Generic Manufacturers to comply with such a duty, they would have violated the sameness principle by sending "Dear Doctor" letters and other communications that surpassed the transmission of information the Brand-Name Manufacturers had communicated.

Consequently, to the extent that the state-law claims depends upon those allegations—and only to that extent—the undersigned recommends finding they are preempted because it would be impossible for the Generic Manufacturers to comply with both federal law and the supposed state law duty. However, Plaintiff has pleaded other marketing-related allegations that support the state law claims against the Generic Manufacturers as members of the class denominated "Marketing Manufacturer Defendants." As such, preemption does not bar any of Plaintiff's state law claims to the extent that they are founded upon allegations that the Generic Manufacturers engaged in aggressive and misleading marketing and inadequate anti-diversion activities.

F. The Generic Manufacturers' Other Arguments

The Generic Manufacturers raise a series of other arguments against Plaintiff's diversion-related RICO and state law claims in the form of bullet points and cross-references to the briefing in *Summit County.* They assert Plaintiff has not pleaded any RICO predicate act to support its failure-to-prevent-diversion theory, but that argument was rejected in *Summit County*,

and is rejected herein. The Generic Manufacturers also argue that Count II and Counts VII-IX should be dismissed because there is no private cause of action under the CSA or the Oklahoma Uniform Controlled Substances Act. As the court explained in *Summit County* and herein, the same argument seeking to dismiss the RICO claim was not persuasive, and the negligence, nuisance, and unjust enrichment claims do not rest upon an in-actionable private right of action under these statutes. (R. 1025, Page ID# 24856-58).

The Generic Manufacturers claim that Counts VII-IX are preempted because they are nothing more than fraud-on-the-DEA claims. The alleged marketing-based claims, as the court explained in *Summit County*, are not premised on a fraud upon the DEA, and thus do not run afoul of *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). (R. 1025, PageID# 24856-57).

Finally, the Generic Manufacturers make the sweeping assertion that Plaintiff "has not pleaded any of the key elements of its state-law claims based upon [the failure to prevent diversion] theory, including any misconduct, causation, or a cognizable injury. Joint MTD Part I-IV; *Summit* MTD at 40-53." (R. 929, PageID# 21150). The court found otherwise in *Summit County* and the Generic Manufacturers' limited argument presents no compelling reason to alter that recommendation here.

For the foregoing reasons, it is recommended that the Generic Manufacturers' Motion to Dismiss be denied, except with respect to the limited theory of liability found preempted above—that the Generic Manufacturers failed to provide additional warnings beyond the FDA-approved labeling of the Brand-Name Manufacturers.

G. Medical Cost Recovery Act

Manufacturers argue that to the extent Plaintiff and the Blackfeet[30] are seeking damages for medical expenses paid by the tribe with funds provided under the Indian Self Determination and Education Assistance Act ("ISDEAA"), those claims should be dismissed. (R. 933-1, PageID# 21232). For those expenses, Manufacturers assert that the only cause of action available to Plaintiffs is one under the Medical Cost Recovery Act, 25 U.S.C. § 1621e ("MCRA"). They further argue the FAC is deficient because it does not identify specific individuals who have been injured. (R. 933-1, PageID# 21233); *U.S. v. Philip Morris, Inc.*, 153 F. Supp. 2d 32 (D.D.C. 2000) (finding that a claim under the MCRA must identify the persons whose medical expenses are sought through the action). They argue that *U.S. v. Standard Oil* Co., 332 U.S. 301 (1947) mandates that an action under the MCRA is the only avenue for recovery of these damages. (R. 933-1, PageID# 21232).

Plaintiff insists it is not suing under the MCRA, and that it is entitled to sue under state tort law. (R. 1008, PageID# 23974). Plaintiff asserts that although the MCRA creates a federal statutory right of recovery, that cause of action does not displace their right to pursue state law claims alleged in their FACs. *Id*., PageID# 23981-82. Consequently, Plaintiff argues that MCRA's supposed pleading requirements are not relevant to this case. *Id*., PageID# 23974.

In *Standard Oil*, the United States sought to recover the cost of healthcare it provided to a soldier who was injured by a third party tortfeasor. 332 U.S. 301, 302. The Supreme Court ruled that it could not pursue recovery under state common law theories. *Id.* at 311. Rather, the federal government would have to rely on either federal common law or await Congressional action

[30] Manufacturers have raised this statutory standing argument with respect to both the Muscogee and the Blackfeet Tribes complaints. The analysis and result are the same in both cases.

creating a right of recovery. *Id.* Concluding that this was not an appropriate case for the invocation of federal common law, the Court ruled that until Congress acted to create a remedy, the government would have no legal means of recovery.[31] *Id.* at 314-17.

Manufacturers present several theories claiming Plaintiff's claims are analogous to the United States' claim in *Standard Oil*, and thus can be brought only under federal law, here the MCRA. (R. 1089, PageID# 27221). This is so, they assert, because the "relationship between the United States and recognized Indian tribes is distinctively and exclusively a creation of federal law," that "affects the Government's purse," and whose "characteristics were fundamentally derived from federal sources and governed by federal authority." (R. 1089, PageID# 27221-22) (internal quotation marks omitted). Manufacturers, however, have cited no case law applying *Standard Oil* to deny Indian tribes the ability to sue under state law; rather, they rely solely on the analogy to *Standard Oil* and the failure of the Tribes to cite any case precisely analogous to the present case in which a tribe sued a third party tortfeasor under state law to recover medical costs incurred by a tribal citizen.

Manufacturers place special emphasis on the source of the funds used by the Tribes to furnish medical care to their citizens, as a means to implicate the portion of the *Standard Oil* analysis that invokes the "Government's purse." But this is where the analogy between the two cases breaks down. First, Plaintiff alleges that it uses funds from numerous sources to fund its healthcare services: "funds received via its [Indian Health Services] compact or funds received by Plaintiff from other sources such as taxes, royalties, tribal businesses, contracts, and grants." (R. 1008, PageID# 23975-76). Second, Plaintiff asserts that "[f]unds received under an ISDEAA

[31] Manufacturers assert that until Congress passed the Medical Cost Recovery Act in 1962, the Federal Government had no remedy in cases like *Standard Oil*. Congress amended the MCRA in 1992 and again in 2010 to allow tribes to recover "damages, reimbursement, or indemnification" from third-party tortfeasors. (R. 1089, PageID# 2720-22)

compact or contract are tribal funds, to be budgeted and spent to provide healthcare as the Tribe deems best." (R. 1008, PageID# 23975).[32]

Plaintiff cites several cases recognizing an Indian tribe's authority to sue under state causes of action to recover for harm to its citizens or members. In *Quapaw Tribe of Oklahoma v. Blue Tee Corp.*, 653 F.Supp.2d 1166 (2009), the Quapaw Tribe sued several mining defendants under the *parens patriae* doctrine alleging, *inter alia*, public and private nuisance and negligence for harms to privately owned lands within the tribe's territory. The court allowed the state common law claims to proceed, holding that the Tribe had asserted a "quasi-sovereign interest" in the health and well-being of its citizens sufficient to establish standing. *Id*. at 1183-84.[33]

Even more persuasive, the MCRA section 1621e, by its terms, does not preempt state law causes of action, but expressly preserves them through two saving clauses. Section 1621(k) states: "Nothing in this section shall be construed to limit any right of recovery available to the United States, an Indian tribe, or tribal organization under the provisions of any applicable Federal, state or tribal laws, including medical lien laws." Section 1621(c) states: "No law of any state...shall prevent or hinder the right of recovery of the United States, an Indian tribe, or tribal organization under subsection (a)." Subparagraph (k) expresses a Congressional intent not to

[32] Plaintiff notes that IHS funds received from the federal government in connection with a compact awarded under the ISDEAA Title V are governed by 25 U.S.C. § 5386(e), which permits a tribe to "redesign or consolidate programs, services, functions, and activities (or portions thereof) included in a funding agreement...and reallocate or redirect funds for such programs, services, functions, and activities...in any manner which the Indian tribe deems to be in the best interest of the health and welfare of the Indian community being served" so long as the "redesign or consolidation does not have the effect of denying eligibility for services to population groups otherwise eligible to be served under applicable Federal law." *Id.*; (R. 1008, PageID# 23975).

[33] *See also Red Lake Band of Chippewa Indians v. U.S.*, 926 F.2d 1320 (1991) (tribe sued U.S. Government for negligence of federal agents; negligence claim for property damage allowed under state tort law, pursuant to Federal Tort Claims Act); *Gila River Indian Community v. Henningson, Durham & Richardson*, 626 F.2d 708 (9th Cir. 1980) (declining to create a federal common law cause of action for breach of contract where commercial agreements between tribes and private citizens could be "adequately protected by well-developed state contract laws"); *Grand Traverse Band of Ottawa and Chippewa Indians v. Blue Cross Blue Shield of Michigan*, No. 14-CV-111349, 2017 WL 3116262, at *7 (E.D. Mich. July 21, 2017) (allowing state law claim for breach of contract to survive motion to dismiss).

preempt state law, while subparagraph (c) expresses an intent to make the right of recovery under subparagraph (a) cumulative of other rights available under state law.

The court does not agree with Manufacturers' assertion that MCRA provides the exclusive remedies for Plaintiff to recover for injuries alleged. Therefore, Manufacturers have not shown that Plaintiff's claims fail to state a viable claim, even to the limited extent that they seek to recover damages for medical care furnished with funds procured pursuant to an ISDEAA compact.

H. Count Three: Lanham Act

Defendants have moved to dismiss this claim, arguing that Plaintiff is not a proper plaintiff under the act. (R. 933-1, PageID# 21239). The court agrees; Plaintiff is not a proper plaintiff under the Lanham Act because it has not alleged an "injury to a commercial interest in reputation or sales" as required to have standing. *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118 (2014). Defendants further argue that Plaintiff lacks standing to sue under the Lanham Act because it is not their competitor. (R. 933-1, PageID# 21239, citing *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2234 (2014) (although "in the end, consumers benefit from the Act's proper enforcement, the cause of action is for competitors, not consumers.")).

Plaintiff argues that it has standing because it suffered injury to its commercial interests as a result of patients being diverted away from Plaintiff's medical facilities. (R. 1008, PageID# 24079). This claim alleges all Defendants have violated the Lanham Act through their alleged misleading statements regarding the safety and efficacy of opioids, and their efforts to prevent diversion, which lead "patients from hospitals and clinics run by Plaintiff" to "seek[] care from doctors and clinics who prescribed high dosages of opioids." (R. 731, PageID# 17196). It asserts

that but for these misrepresentations, patients "would have sought alternative, safer forms of treatment offered by Plaintiff's hospitals and clinics" and "would not have sought treatment from doctors and clinics who prescribed high dosages of opioids because they would not have been able to obtain excessive and unnecessary quantities of opioids as a result of their treatment." *Id.*

> The Lanham Act provides in pertinent part:
>
> Any person who, on or in connection with any goods or services ... uses in commerce any ... false or misleading description of fact, or false or misleading representation of fact, which –
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics [or] qualities ... of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B). In *Lexmark*, Static Control, a manufacturer and seller of components used in Lexmark's printer toner cartridges, sued Lexmark under the Lanham Act, alleging that Lexmark had engaged in false advertising that harmed Static Control's business reputation and caused it to lose sales. 572 U.S. 120-22. The Supreme Court explained that standing extends only to a plaintiff whose interests "fall within the zone of interests protected" by the Lanham Act, and to one "whose injuries are proximately caused by violations of the statute." 572 U.S. 118, 129, 132. After referring to the Act's own "unusual, and extraordinarily helpful" statement of its purposes as a guide to determining the contours of the "zone of interests" protected by the Act, the Supreme Court indicated:

> The intent of this chapter is to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce, to protect registered marks used in such commerce from interference by State, or territorial legislation; to protect persons engaged in such commerce against unfair competition; to prevent fraud and deception in such commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions

> respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

Id. at 131.

The Court explained that "a plaintiff suing under § 1125(a) ordinarily must show economic or reputational injury flowing directly from the deception wrought by the defendant's advertising; and that that occurs when deception of consumers causes them to withhold trade from the plaintiff." *Id.* at 133. The Court held that standing under a zone of interests analysis requires that "a plaintiff must allege an injury to commercial interest in reputation or sales." *Id.* at 131-32. In addition, Lanham Act standing requires a plaintiff to plead both standing and proximate cause. 572 U.S. 140 ("To invoke the Lanham Act's cause of action for false advertising, a plaintiff must plead (and ultimately prove) an injury to a commercial interest proximately caused by the defendant's misrepresentations. Static Control has adequately pleaded both elements.").

Although Plaintiff frames its harm in commercial terms – "Plaintiff, through its hospitals and clinics, is engaged in commerce" – the real interest they seek to protect is in the physical well-being of its citizens, and the fiscal health of its government. (R. 1008 PageID# 24082). These interests, on the facts alleged in the FAC, do not fall within the zone of interests protected by the Lanham Act. Plaintiff urges the court to take a broad view of standing under *Lexmark*, arguing that the *Lexmark* Court rejected the proposition "that only direct competitors have statutory standing." *Lexmark*, 572 U.S. at 136 ("a rule categorically prohibiting all suits by noncompetitors would read too much into the Acts reference to 'unfair competition.'") (R. 1008, PageID# 24082). The language quoted by Plaintiff was excerpted from the Court's discussion of proximate causation, not its zone of interests analysis. Moreover, the Court's reference to "direct competitors" arose in response to Lexmark's argument that the court should apply a "direct

competitor test" for proximate causation–a test that would have excluded Static Control's claim. The Court's unwillingness to limit a finding of proximate cause on the basis of whether a commercial actor was a direct or indirect competitor does not support Plaintiff's request to have this court expand the scope of permissible causes of action under the Lanham Act's zone of interests analysis.

The court concludes that Plaintiff's allegations concerning the loss of patients who might have received treatment at its hospitals and clinics are not sufficient to constitute an injury to its "commercial interest in reputation or sales," under the Lanham Act. *Lexmark*, 572 U.S. at 131-32. Consequently, Plaintiff lacks standing under the Lanham Act and its claim should be dismissed in its entirety as against all Defendants.[34]

I. Counts IV and VII: Nuisance

1. Oklahoma Nuisance Law

Oklahoma defines a "public nuisance" as "one which affects at the same time an entire community or neighborhood, or any considerable number of persons, although the extent of the annoyance or damage inflicted upon the individuals may be unequal." Okla. Stat. tit. 50, § 2. The nuisance statute provides:

> A nuisance consists in unlawfully doing an act, or omitting to perform a duty, which act or omission either:
>
> First. Annoys, injures or endangers the comfort, repose, health, or safety of others; or
>
> Second. Offends decency; or
>
> Third. Unlawfully interferes with, obstructs or tends to obstruct, or renders dangerous for passage, any lake or navigable river, stream, canal or basin, or any public park, square, street or highway; or

[34] The court notes that the "injury to business or property" requirement under RICO is a distinct analysis that is not coterminous with the Lanham Act's "commercial interest in sales or reputation" requirement.

> Fourth. In any way renders other persons insecure in life, or in the use of property, provided, this section shall not apply to preexisting agricultural activities.

Id., § 1.

The complaint asserts a nuisance cause of action against Manufacturers for having "committed offenses against the public order and economy of the [Muscogee] Nation" based on alleged unlawful and misleading marketing practices, (R. 731, Count IV, ¶¶420-422), and in a separate nuisance cause of action alleges that the all Defendants' offenses include the failure to monitor, halt, and report suspicious orders, (*id.*, Count VII, ¶¶452-454). Both counts allege that the Defendants' respective activities interfere with commonly held rights to public health, safety, and wellbeing, among others, resulting in the opioid epidemic—a continuing public nuisance. (*Id.*, ¶¶424-425, 427, 457, 460). Defendants contend that Oklahoma law limits actionable nuisance claims to those that relate to land and real property, and therefore does not recognize claims relating to the manufacture and sale of alleged harmful products. They further assert that dismissal is warranted based on a failure to allege interference with a public right and control over the instrumentality at the time the claimed injuries were sustained.[35]

2. Interference with Property Right Limitation

Defendants assert that Oklahoma nuisance law demonstrates a "consistent theme" of a concern with the misuse of, or interference with, land and real property. Citing Oklahoma decisions concerning various property-related issues, they argue that Plaintiff's product-based

[35] The Generic Manufacturers incorporate Manufacturers' briefs (R. 933-1 and R. 1089) and Manufacturers' *Summit County* briefs (R. 499-1 and R. 746). *See* R. 929-1, PageID# 21149-21150, 21151; R. 1090, PageID# 28390, 27394. The Pharmacies refer to their briefs in support of the motion to dismiss the public nuisance claim asserted in the Broward County action (R. 582-1, PageID# 14448-14449; R. 825, PageID# 19567-19569), adopt and incorporate the arguments asserted in Distributors' brief in this action, and they also adopt and incorporate Manufacturers' arguments in this action (R. 933-1 and R. 1089). *See* R. 928-1, PageID# 21100.

nuisance theories fail to allege a plausible connection with property rights, and should be dismissed as improperly departing from Oklahoma's "legal tradition." (R. 933-1, PageID# 21246-21247; R. 925-1, PageID# 21042 & n.12, citing *Laubenstein v. BoDe Tower, L.L.C.*, 392 P.3d 706, 709 (Okla. 2016); *N.C. Corff P'ship, Ltd. v. OXY USA, Inc.*, 929 P.2d 288, 293-96 (Okla. Civ. App. 1996); *Fairlawn Cemetery Ass'n v. First Presbyterian Church,* U.S.A., 496 P.2d 1185, 1187 (Okla. 1972); *Meinders v. Johnson*, 134 P.3d 858, 860, 867-868 (Okla. Civ. App. 2005)). Defendants' argument sweeps too broad, as none of these decisions expressly limits the cause of action to claims relating to property. Nor do Defendants cite any Oklahoma decision, or any decision from a federal court construing Oklahoma law, that rejects a public nuisance claim on the basis that it alleged something other than harm to property.

Defendants contend that this absence of precedent supports an inference that Plaintiff's claims are not recognized by Oklahoma law, cautioning that the Sixth Circuit has voiced a reluctance to "speculate on any trends of state law." (R. 1089 PageID# 27236-27267; R. 928-1, PageID# 21111, citing *Combs v. Int'l Ins. Co.*, 354 F.3d 568, 575-577 (6th Cir. 2004) ("When given a choice between an interpretation of [state] law which reasonably restricts liability, and one which greatly expands liability, we should choose the narrower and more reasonable path.") (internal quotation marks and citation omitted)). Some courts in other jurisdictions have concluded that an absence of precedent applying nuisance theory to claims that were not related to property infers that the claim is not cognizable. *See Tioga Pub. Sch. Dist. No. 15 v. U.S. Gypsum Co.*, 984 F.2d 915, 920-921 (8th Cir. 1993). Others conclude that the absence of nuisance precedent outside of the property context was "due to the happenstance of how the particular public nuisance actions arose and not to any principle of law." *See, e.g., City of Gary ex rel. King v. Smith & Wesson Corp.*, 801 N.E.2d 1222, 1232–1233 (Ind. 2003).

The role of this court when addressing an issue on which the Oklahoma Supreme Court has not ruled, is to predict that court's likely interpretation, guided by sources that include "the decisions (or dicta) of the [State] Supreme Court in analogous cases, pronouncements from other [of the State's] courts, restatements of law, commentaries, and decisions from other jurisdictions." *State Auto Prop. & Cas. Ins. Co., v. Hargis*, 785 F.3d 189, 195 (6th Cir. 2015).

Acknowledging the scarcity of Oklahoma precedent addressing public nuisance claims in contexts other than land or property use, the court is not persuaded that the state's law is necessarily restricted to a property-related context for the following reasons. First, Defendants' theory would have the court ignore the literal language of the Oklahoma nuisance statute. The Oklahoma Supreme Court instructs that

> [t]he primary goal of statutory interpretation is to determine and follow the legislature's intention. That intent is ascertained from the whole act in light of its general purpose and objective. If the language is plain and clearly expresses legislative will, further inquiry is unnecessary.

Dean v. Multiple Injury Tr. Fund, 145 P.3d 1097, 1101 (Okla. 2006) (citations omitted). The language of Okla. tit. 50, § 1 does not restrict nuisance liability to acts or omissions relating to property. The statute unequivocally identifies a nuisance as including the commission of unlawful acts or omissions of duty that "renders other persons insecure in life, *or* in the use of property…." *Id.* (emphasis added). The 'use of property' clause is disjunctive, not exclusive.[36]

Moreover, Oklahoma law provides that the common law continues "in aid of the general statutes of Oklahoma." Okla. Stat. tit. 12, § 2 ("The common law, as modified by constitutional and statutory law, judicial decisions and the condition and wants of the people, shall remain in

[36] Distributors argue that a property limitation is demonstrated by the statutory clause that subjects successive owners to abatement liability for property found to be a nuisance. Okla. Stat. tit. 50, § 5. (R. 1086, PageID# 27082). The argument is not well taken. Although that clause imposes liability on property owners for failing to abate a preexisting and continuing nuisance, it does not restrict nuisance claims brought under Title 50 to those allegedly arising from the use or misuse of property.

force in aid of the general statutes of Oklahoma"). Therefore, this court's determination of the Oklahoma Supreme Court's likely ruling on the Defendants' 'property-related' defense is informed by that court's view,

> Inherent in the common law is a dynamic principle which allows it to grow and to tailor itself to meet changing needs within the doctrine of stare decisis, which, if correctly understood, was not static and did not forever prevent the courts from reversing themselves or from applying principles of common law to new situations as the need arose.***
>
> This Court has similarly followed the concept that the common law is a dynamic and growing thing and its rules arise from the application of reason to the changing condition of society. The common law is not static.

Brigance v. Velvet Dove Rest., Inc., 725 P.2d 300, 303 (Okla. 1986) (citations and internal quotation marks omitted). The statement indicates that the Oklahoma Supreme Court anticipated that the common law would adapt to address previously unanticipated situations and its reasoning supports the court's conclusion that an absence of judicial precedent need not bar a remedy where, as here, unprecedented circumstances arise.

Furthermore, although not binding on this court, in the absence of appellate authority, Oklahoma trial court decisional law may inform its determination. *Pittman v. Experian Info. Sols., Inc.*, 901 F.3d 619, 636 (6th Cir. 2018) ("The Court may use the decisional law of the state's lower courts [and] other federal courts construing state law …."). Plaintiff cites two Oklahoma cases acknowledging the validity of public nuisance claims that are unrelated to land or real property, one of which denied a motion to dismiss a public nuisance claim in a recent case based on defendant opioid manufacturers' alleged fraudulent marketing practices. *See State of Oklahoma ex rel. Hunter v. Purdue L.P.*, No. CJ-2017-816 (Okla. Dist. Ct. Dec. 6, 2017);[37] *State*

[37] Distributors contend that because the defendants in *Oklahoma ex rel. Hunter* did not argue that property use was a prerequisite to an Oklahoma nuisance action, this court should not infer anything from the denial of the motion to dismiss. (R. 1086, PageID# 27081 referring to R. 1086-1, PageID# 27141-27142). The Oklahoma district court did, however, broadly hold that "the State's Petition sufficiently states its claims and those claims should not be

of Oklahoma v. R.J. Reynolds, No. CJ 96-1499 (Okla. Dist. Ct. Nov. 5, 1998) (holding that public nuisance claim seeking recovery for smoking related health care costs would survive summary judgment). In finding the plaintiff's claim sufficient to survive dismissal, the *Oklahoma ex rel. Hunter* court joined others that recognized the viability of public nuisance claims asserted in opioid cases based on allegations analogous to Plaintiff's claims.[38]

The court construes the foregoing as legislative and judicial indications that the Oklahoma Supreme Court would likely recognize Plaintiff's public nuisance claims, not as imprudent substantive expansions of the law, but as stating viable theories of recovery.

3. Products Liability Limitation

Defendants urge the court to dismiss Counts IV and VII because they are "essentially products liability claims for economic damages masquerading under the guise of nuisance law" and because there is no Oklahoma Supreme Court precedent affirming the viability of a claim that "collapses the critical distinction between nuisance and products liability." (R. 933-1, PageID# 21245). They argue that if public nuisance is expanded to embrace product-based claims, liability would proliferate against manufacturers, distributors, and retailers by, for example, relaxing causation standards or relieving a plaintiff's burden to identify the particular allegedly culpable product. (R. 933-1, PageID# 21248-21249, citing *City of St. Louis v.*

---

dismissed based on preemption or pursuant to the Primary Jurisdiction doctrine or the Court's inherent power" (R. 1008-3, PageID# 24096), an unlikely conclusion if, as Defendants argue, Oklahoma law recognized only property-based nuisance claims.

[38] *See State of New Hampshire v. Purdue Pharma, L.P.*, 217-2017-CV-00402 (N.H. Super. Ct. Sept. 18, 2018) (R. 1008, Ex. D); *State of Ohio ex rel. DeWine v. Purdue Pharma, L.P.*, No. 17 CI 261 (Ohio Ct. C.P. Ross Cty. Aug. 22, 2018) (*id.*, Ex. E); *State of Alaska v. Purdue Pharma L.P.*, No. 3AN-17-09966CI (Alaska Super. Ct. July 12, 2018) (*id.*, Ex. F); *In re Opioid Litig.*, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) (*id.*, Ex. G); *State of Washington v. Purdue Pharma*, No. 17-2-25505-0 SEA (Wash. Super. Ct. May 14, 2018) (*id.*, Ex. H); *State of West Virginia ex rel. Morrisey v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Apr. 17, 2015) (*id.*, Ex. J); *State of West Virginia ex rel. Morrisey v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Feb. 19, 2016) (*id.*, Ex. K).

Benjamin Moore & Co., 226 S.W.3d 110, 113, 116 (Mo. 2007); *State v. Lead Indus. Ass'n*, 951 A.2d 428, 456-457 (R.I. 2008)). They further maintain that if the misuse of an otherwise legal product were deemed to constitute interference with public rights, that concept would stretch to the extent of rendering "any potentially dangerous instrumentality" actionable. *See City of Chicago v. Beretta U.S.A. Corp.,* 821 N.E.2d 1099, 1116 (Ill. 2004).

These arguments rely on caselaw that refuses to recognize public nuisance liability based on the manufacture, distribution or sale of lawful products in the absence of alleged culpable conduct by defendants who also lack control over the product at issue at the time the alleged injury occurred and therefore cannot abate the nuisance. *See, e.g., Camden Cty. Bd. of Chosen Freeholders v. Beretta, U.S.A. Corp*., 273 F.3d 536, 538-542 (3d Cir. 2001); *Lead Indus. Ass'n,* 951 A.2d at 449-450, 456; *City of Philadelphia v. Beretta U.S.A. Corp.*, 126 F. Supp. 2d 882, 910-911 (E.D. Pa. 2000); *Penelas v. Arms Tech. Inc.*, 1999 WL 1204353, *4 (Fl. Cir. Ct. Dec. 13, 1999).[39] Those decisions, however, are based on alleged facts that differ materially from those Plaintiff alleges. Contrary to the Defendants' contentions, while Plaintiff's nuisance theory concerns a product, it does not sound in products liability. The FAC alleges that the nuisance arises from the Defendants' misconduct, not from alleged harm caused by the use or misuse of an otherwise legal prescription opioid product. Plaintiff alleges that the nuisance is the result of fraudulent marketing that misstated the safety and efficacy of opioids in order to ensure widespread use and the failure to create and maintain controls against theft, diversion and misuse

[39] *See also, City of Chicago v. Beretta*, 821 N.E.2d at 1116-1117; *Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 671-672 (8th Cir. 2009); *Detroit Bd. of Educ. v. Celotex Corp.*, 493 N.W.2d 513, 520 - 522 (Mich. Ct. App. 1992); *Tioga Pub. Sch. Dist.* 984 F.2d at 920-921. The Pharmacies and Manufacturers cite the Restatement (Third) of Torts: Liability for Economic Harm § 8 cmt. g (Tentative Draft No. 2, 2014) for the proposition that "the common law of public nuisance is an inapt vehicle for addressing the conduct at issue" where dangerous products are concerned. (R. 933-1; PageID# 21248, n.11; R. 1087, PageID# 21767). Plaintiff responds that Oklahoma has not adopted the Third Restatement, which is still in draft form. (R. 1008, PageID# 24019 n. 200).

of prescription opioids from the legal supply chains that lead to an illicit secondary market. (*E.g.*, R. 731, ¶¶ 423-424, 452; *see also* ¶¶ 2-3, 10-12, 14-15). These allegations make clear that the claimed nuisance is the alleged consequence of the Defendants' conduct and not the opioid product itself.

4. Control Over the Instrumentality of the Nuisance

Distributors contend that they cannot be held liable for maintaining a nuisance that they did not control, at the time, the alleged consequential injuries occurred. *See Burlington N. & Santa Fe Ry. Co. v. Grant*, 505 F.3d 1013, 1026 (10th Cir. 2007). They argue that Plaintiff fails to plausibly allege control by claiming that Distributors directed, sanctioned or actively participated or cooperated in the injurious conduct that produced the illegal market, explaining that as "middlemen" they receive medication from manufacturers and relinquish control when they deliver and entrust it to pharmacies. (R. 925-1, PageID# 21040-22041; R. 1086, PageID# 27080-27081). The Pharmacies, for their part, similarly assert that they should not be subject to public nuisance liability based on distribution of a lawful product where the claimed injury resulted from misuse by third parties after it left their control. (R. 928-1, PageID# 21111; R. 1087, PageID# 27166, citing *Penelas*, 1999 WL 1204353, at *4 (dismissing nuisance claim based on "criminal or reckless misuse of firearms by third parties beyond the defendants' control")).

Defendants' arguments rest upon a false premise that the instrumentality of the nuisance is the opioid medication. As discussed above, the alleged instrumentality of the nuisance is their creation and fueling of the illicit market. *See, e.g., James v. Arms Tech., Inc.,* 820 A.2d 27, 52 (N.J. Super Ct. App. Div. 2003) ("The 'instrumentality' defendants 'control' is the creation and supply of this illegal [gun] market."). In this regard, Plaintiff states that it does not allege that the

nuisance occurred when individual users ingested opioids, but rather when Distributors and Pharmacies "facilitated diversion," "fail[ed] to implement effective controls against theft, diversion and misuse of prescription opioids from legal supply chains," "failed to design and operate an adequate system to detect halt, and report suspicious orders," and "used property for repeated unlawful sales of prescription opioids" (R. 731, ¶¶452). The FAC states:

> At all times, Diversion Manufacturer Defendants and Distributor Defendants had the power to shut off the supply of illicit opioids into the [Muscogee] Nation, and Diversion Defendants possessed the right and ability to control the nuisance-causing outflow of opioids from pharmacy locations or other points of sale into the surrounding [Muscogee] Nation.

(¶ 262; *see also* ¶¶333, 429, 459, 462). Whether a defendant had a requisite level of control raises questions of fact inappropriate for resolution on a motion to dismiss. *Cf. Burlington N. & Santa Fe Ry. Co.,* 505 F.3d at 1026 (noting an absence of triable issues regarding defendant's responsibility for maintaining a nuisance).

Accepting the allegations above as true, the FAC plausibly alleges that the Defendants had the ability to control the conduct that allegedly resulted in the public nuisance.

5. Public Right

Distributors contend that Plaintiff fails to allege interference with a public right as required by Oklahoma law, arguing that all of the rights alleged are either individual or not rights of any kind. (R. 925-1, PageID# 21042-21044; R. 1086, PageID# 27082-27084). The FAC alleges:

> Diversion Defendants' activities have unreasonably interfered, are interfering, and will interfere with the common rights of the public:
>
> a. to be free from reasonable apprehension of danger to person and property;
> b. to be free from the spread of disease within the community, including the disease of addiction and other diseases associated with widespread illegal opioid use;
> c. to be free from the negative health and safety effects of widespread illegal

drug sales on premises on and around the Nation;

d. to be free from blights on the community created by areas of illegal drug use and opioid sales;

e. to live or work in a community in which local businesses do not profit from using their premises to sell products that serve the criminal element and foster a secondary market of illegal transactions; and

f. to live or work in a community in which community members are not under the influence of narcotics unless they have a legitimate medical need to use them.

(R. 731, ¶¶421, 453). Under Oklahoma law, a public nuisance is a nuisance that "affects at the same time an entire community or neighborhood, or any considerable number of persons." Okla. Stat., tit. 50, § 2; *Long Bell Lumber Co.,* 99 P. 911, 917 (Okla. 1908) ("A common or public nuisance is one that affects the people at large, and is a violation of a public right ….").

Distributors characterize the rights alleged by the Nation as the rights to avoid personal injury, disease or adverse health effects resulting from opioid addiction, and argue that the these are in the nature of individual, private rights that do not affect the public uniformly. (R. 925-1, PageID# 21044-21045, citing *City of McAlester*, 98 P.2d 924, 926 (Okla. 1940) and the Restatement (Second) Torts § 821B cmt. g (1979)). They argue that regardless of the number of people who choose to use opioids, the choice is private and does not impair the exercise of public rights by others. (*Id.,* PageID# 21046).

Further, Distributors contend that "public health" and "public right" are not synonymous. (R. 1086, PageID# 27083-27084, citing *Lead Indus. Ass'n,* 951 A.2d at 448). They describe "public health" as a "colloquial term" used in reference to such problems as obesity, cancer and smoking, whereas "public right" is a legal term that functions to limit the definition of public nuisance. They further maintain that there is no public right to be free either from "the disease of addiction," which is not contagious, or from the risk that individuals will misuse opioids in a way that creates a risk of harm to themselves or others. (*Id.*, PageID# 27084, citing *Chicago v.*

Beretta, 821 N.E.2d at 1116).

Plaintiff argues more persuasively that the Oklahoma nuisance statute creates a cause of action based on unlawful acts or omissions that annoy, injure or endanger the "comfort, repose, health, or safety of others." Okla. Stat. tit. 50. Furthermore, the right to public health as alleged in the complaint has been recognized by courts addressing the issue in the context of opioid litigation. *See, e.g., In re Opioid Litig.*, No. 400000/2017, 2018 WL 3115102 (N.Y. Sup. Ct. June 18, 2018) (noting "defendants' failure to establish why public health is not a right common to the general public nor why such continuing, deceptive conduct as alleged would not amount to interference"); *State of West Virginia ex rel. Morrisey v. Cardinal Health, Inc.*, No. 12-C-140 (W. Va. Cir. Ct. Apr. 17, 2015) (recognizing a right common to the general public "to be free from unwarranted injuries, addictions, diseases and sicknesses" causing ongoing damage, hurt, inconvenience and other adverse consequences to residents).

Like the alleged circumstances in those cases, the FAC describes a purposeful and continuing course of misconduct resulting in a multifaceted crisis with mounting adverse effects upon the government entity and upon the community it serves. In that regard, Plaintiff:

> [B]rings this action in its proprietary capacity and under its *parens patriae* authority in the public interest to protect the health, safety, and welfare of the citizens of the [Muscogee] Nation to stop the opioid epidemic within the [Muscogee] Nation and to recover damages and seek other redress from harm caused by Defendants' improper marketing, sales, distribution, dispensing, and reporting practices related to prescription opioids.

(R. 731, ¶27). It further alleges that the Defendants' misconduct created, contributed to, and maintained the "[Muscogee] Nation's opioid epidemic" that was its foreseeable consequence (*e.g.*, ¶¶15, 275-276, 283, 285-286, 291-292); "undermined and continues to undermine the [Muscogee] Nation's public health, quality of life, and safety" (*e.g.*, ¶¶281, 425, 427, 457, 460); and resulted in a broad range of problems to Plaintiff's citizens (*e.g.*, ¶¶20-21, 294). These

allegations sufficiently plead a right commonly held by Plaintiff's citizens to be free from a crisis of epidemic proportions that interferes with a general common right to public health, safety and welfare—a right exercised through the local government's provision of protective, preventative, and ameliorative services, which Plaintiff alleges are being consumed by the costs attending the opioid crisis. (*e.g.*, ¶¶ 21, 282, 291, 294, 309, 426, 431, 464).

6. Causation

Proximate cause is a requisite element of an Oklahoma public nuisance action. *See Twyman v. GHK Corp.*, 93 P.3d 51, 57-58 (Okla. Civ. App. 2004). As Manufacturers explain, Oklahoma causation standards do not deviate from the general common law and therefore the federal RICO causation standard applies here. *See Perry v. Am. Tobacco Co.*, 324 F.3d 845, 850 (6th Cir. 2003) ("The failure of the [plaintiffs] to demonstrate proximate cause under *Holmes* with respect to their RICO and federal antitrust claims also means that their antitrust and common law claims under [state] law fail for lack of proximate cause."). Accordingly, the court's proximate cause analysis in *Summit County* applies to Plaintiff's claims here, leading to a conclusion that the FAC sufficiently pleads a connection between Defendants' alleged misconduct and Plaintiff's consequential injuries that is both sufficiently direct and foreseeable to cross the plausibility threshold. (R. 1025, PageID# 24832-24838).[40] In addition, other courts have applied a more lenient causation pleading standard in public nuisance actions, for example,

[40] Plaintiff raises a non-persuasive argument that, under Oklahoma law, *Holmes,* 503 U.S. 258, is inapplicable to public nuisance claims. Plaintiff reasons that the primary concern of the *Holmes* court was the recovery of multiple or duplicative money damages, which is not implicated by its claim for abatement of the nuisance. (R. 1008, PageID# 23966). Manufacturers reply that Plaintiff's position lacks support and argue that if the alleged conduct is not the legally cognizable cause for the claimed injuries, then a remedy, whether damages or abatement, is not justified. (R. 1089, PageID# 27215 n.6, citing *CSX Transp., Inc. v. McBride*, 564 U.S. 685, 701 (2011) (explaining that proximate cause embodies "the policy-based judgment that not all factual causes contributing to an injury should be legally cognizable causes")). The court agrees, but the point does not alter the determination reached in *Summit County* and above.

stating:

> The tortious actions or omissions of a defendant or defendants need not be the immediate cause of injury to the public. If a defendant's conduct 'remains the dominant and relevant fact without which the public nuisance would not have resulted where and under the circumstances it did,' it may be held liable for setting in motion or being a force in the sequence of events resulting in injury to the public. Intervening actions, even multiple or criminal actions taken by third parties, do not break the chain of causation if a defendant could reasonably have expected their nature and effect.

City of New York v. Beretta U.S.A. Corp., 315 F. Supp. 2d 256, 282 (E.D.N.Y. 2004) (internal citations omitted); *see also NAACP v. AcuSport, Inc.*, 271 F. Supp.2d 435, 497 (E.D.N.Y. 2003) ("[W]here the welfare and safety of an entire community is at stake, the cause need not be so proximate as in individual negligence cases.").[41]

Based on the forgoing, the court finds that Counts IV and VII plead plausible rights to relief under a nuisance theory.

J. Counts V and VIII: Negligence

Under Oklahoma law, the elements for negligence claim include: "1) a duty owed by the defendant to protect plaintiff from injury, 2) failure to fulfill that duty, and 3) injuries to plaintiff proximately caused by defendant's failure to meet the duty." *Fargo v. Hays*-Kuehn, 352 P.3d 1223, 1227 (Okla. 2015). Plaintiff alleges that Manufacturers have a common law duty to "make a full and fair disclosure as to the matters about which they choose to speak" (R. 731 at ¶ 101), and to "exercise reasonable care in marketing and selling opioids." (R. 731 at ¶ 99). Plaintiff also

[41] The court notes that Plaintiff, responding to a general reference by the Generic Manufacturers to the Joint Manufacturers' brief in support of their motion to dismiss in *Summit County*, addresses the economic loss doctrine arguments asserted therein. Because the Generic Manufacturers do not develop the theory that the economic loss doctrine serves to negate recovery for an alleged public nuisance under Oklahoma law, or respond to Plaintiff's arguments, the court does not reach the issue.

alleges that Distributors and Pharmacies owed a common law duty to "prevent the diversion of dangerous opioid products." (R. 1008, PageID# 24030; R. 731 at ¶ 467-68).

Defendants challenge the sufficiency of the FAC with respect to the existence of a common law duty of care. (R. 933-1, PageID# 21228; R. 925-1, PageID# 21036; R. 928-1, PageID# 21106-07). They argue that Oklahoma law does not impose on them a duty to prevent the wrongful acts of third persons, which they contend the FAC actually alleges. (R. 933-1, PageID# 21228-30; R. 925-1, PageID# 21039-40; R. 928-1, PageID# 21107-08). The Pharmacies also raise the learned intermediary doctrine. (R. 928-1, PageID# 21107-08). Finally, all Defendants argue that Plaintiff has failed to adequately plead proximate cause. (R. 933-1, PageID# 21215-28 ; R. 925-1, PageID# 21046-48; R. 928-1, PageID# 21102-04).

Defendants raised all of these arguments in *Summit County* and in each case, the court rejected them. (R. 1025, PageID# 24880-89).[42] In *Summit County* case, the court concluded that the plaintiffs had pled sufficient facts to plausibly make out a claim that all the defendants owed them a duty of care. (R. 1203, PageID# 29052-54). The parties have not identified, and the court has not found any Oklahoma authority that would lead to a different result with respect to the sufficiency of Plaintiff's negligence claim. Plaintiff has pled facts sufficient to satisfy the elements of their negligence action.[43]

Distributors, however, raise one argument that was not present in *Summit County*, namely that they are exempt from negligence actions under an Oklahoma statutory provision that limits a

[42] Distributors also assert, in one brief paragraph, that the Complaint fails to allege facts suggesting that they breached their duties. (R. 925-1, PageID# 21040). This argument was not addressed in *Summit County*, and it requires little analysis here. The Complaint contains numerous allegations that Distributors breached their duty of care by, e.g. "oversupplying the market on and around the Nation with highly addictive prescription opioids" and "using unsafe distribution and dispensing practices." (R. 731 at ¶ 468).

[43] The court declines to further address Defendants' arguments with regard to a negligence per se theory, as Plaintiff has sufficiently pled a common law duty.

non-manufacturing distributor's liability for negligence claims. They argue that Plaintiff's negligence claim is barred against them by Oklahoma's "Innocent Seller" statute, which they assert limits a non-manufacturing distributor's liability for negligence claims. (R. 925-1, PageID# 21034-35). Plaintiff argues that the Oklahoma statute is inapplicable because it is limited to product liability claims. It asserts that the statute is intended to protect sellers of defective products that were not responsible for the defect, not having designed, assembled, or inspected it. It further contends that the statute has no applicability to this case, in which the Distributor's negligence liability is premised on their "failure to take steps to prevent the diversion of opioids." (R. 1008, PageID # 24036).

In Oklahoma, a "plaintiff injured by a defective product can utilize various theories to recover for injuries caused by the product. A product liability action may be based on a theory of negligence liability or strict products liability." *Loomis v. Specialized Desanders, Inc.*, No. CIV-18-525-C, 2018 WL 4355205, *1 (W.D. Okla. Sept. 12, 2018) (noting potential lability for "middlemen" in the distribution chain and discussing the Oklahoma legislature's passage of section 57.2(E) to create a rebuttable presumption limiting their liability in product liability actions). "Even with the advent of strict products liability, the negligence cause of action remains available to a plaintiff injured by a defective product." *Id.* Oklahoma law codifies a non-manufacturer, product seller's duties, at section 57.2(G), as follows:

> A product seller other than a manufacturer is liable to a claimant on the basis of negligence if the claimant establishes that
>
> 1. The product seller sold the product involved in such action;
>
> 2. The product seller did not exercise reasonable care;
> a. In assembling, inspecting, or maintaining such product, or
> b. In passing on warnings or instructions from such product's manufacturer about the dangers and proper use of such product; and

> 3. Such failure to exercise reasonable care was a proximate cause of the harm complained of by the claimant.

Okla. Stat. tit. 76, § 57.2(G). Distributors assert that the FAC contains no allegations that they failed to exercise reasonable care in assembling, inspecting or maintaining the opioids, or in passing on warnings or instructions from Manufacturers about the dangers and proper use of the opioids, and thus Plaintiff has failed to satisfy the statutory elements necessary to state a claim for negligence as against them. (R. 925-1, PageID# 21035).

Distributors, however, have cited no Oklahoma case law or legislative history demonstrating that this statute displaces all common law negligence claims, or applying this statutory section outside a product liability action. Plaintiff has the more persuasive argument, as their negligence claim does not seek to hold Distributors liable for distributing a defective product; and, therefore, Distributors have not shown that Plaintiff's negligence claim must be dismissed.

K. Counts VI and IX: Unjust Enrichment

In Counts Six and Nine, Plaintiff asserts an unjust enrichment claim against all Defendants (R. 731, PageID# 17202-03, 17208-09).

The Oklahoma Supreme court has explained that "unjust enrichment is a condition which results from the failure of a party to make restitution in circumstances where it is inequitable; i.e., the party has money in its hands that, in equity and good conscience, it should not be allowed to retain." *Harvell v. Goodyear Tire & Rubber Co.*, 164 P.3d 1028, 1035 (Okla. 2006). That Court has also held that "unjust enrichment arises not only where an expenditure by one person adds to the property of another, but also where the expenditure saves the other from expense or loss." *McBride v. Bridges,* 215 P.2d 830, 832 (Okla. 1950); *City of Tulsa v. Bank of Oklahoma, N.A.*, 280 P.3d 314, 319 (Okla. 2011) ("[T]here must be enrichment to another,

coupled with resulting injustice); *see also Am. Biomedical Grp., Inc. v. Techtrol, Inc.*, 374 P.3d 820, 828 (Okla. 2016) ("One is not unjustly enriched...by retaining benefits involuntarily acquired which law and equity give him absolutely without any obligation on his part to make restitution.").

Plaintiff bases its unjust enrichment claim against the Marketing Manufacturer Defendants on the allegation that they made substantial profits from selling their opioids "while fueling the opioid epidemic in the [Muscogee] Nation." (R. 731, ¶ 449). The benefits of these activities went entirely to the Defendants while a great many of the costs were borne by Plaintiff. (*Id*. at ¶ 447). Similarly, as to the Diversion Defendants, Plaintiff alleges that it has borne the costs of their profit-making activities. In so doing, Plaintiff has conferred a benefit upon the Defendants, which the Defendants knowingly retained, under circumstances in which it would be unjust for the Defendants to retain that benefit. With respect to all Defendants, Plaintiff alleges that it would be unjust for the Defendants to retain the benefits Plaintiff has conferred. (*Id.* at ¶¶ 450, 484).

Defendants raise several arguments in support of their Motions to Dismiss the unjust enrichment counts. Manufacturers and Distributors argue that they have not received any benefit from Plaintiff. (R. 933-1, PageID# 21251; R. 925-1, PageID# 21048-49). Manufacturers and Distributors both argue that since they never had an obligation to pay the public costs of the opioid crisis, they could not be unjustly enriched by Plaintiff's payment of those costs. (R. 933-1, PageID# 21252; R. 925-1, PageID# 21048). Distributors further argue that Plaintiff's payments of the costs of the crisis "do not add anything to Distributors' property, nor do they protect Distributors from any expense or loss that they otherwise would have to pay." (R. 1086, PageID# 27091, citing *City of Tulsa*, 280 P.3d, 319).

These arguments, taken together, amount to a claim that Plaintiff's allegations of unjust enrichment fail because there was no transfer payment from Plaintiff to the Defendants, and because the Defendants had no previously existing legal obligation to pay these costs. As a result, Defendants argue Plaintiff's payments for extraordinary costs and public services are irrelevant to them–they do not enrich the Defendants. Plaintiff's claim, however, relies on the theory that by paying the economic costs and negative impact of the Defendants' business practices—their negative externalities—Plaintiff is sparing the Defendants from realizing the costs of their economic activities.

Defendants assert that no Oklahoma court has recognized such a theory. (R. 928, PageID# 2112; R. 1089; PageID# 27242; R. 1086, PageID# 27091). Indeed, the Oklahoma Supreme Court has not had the occasion to rule on the externality theory as a basis for an unjust enrichment claim and the parties cite conflicting case law either espousing or rejecting this theory.[44] The court has reviewed those cases and finds that none of the cases rejecting the theory presents a persuasive reason for this court to depart from its prior holding in *Summit County*. (R. 1025, PageID# 24897-24901; *see also White v. Smith & Wesson*, 97 F. Supp. 2d 816, 829 (N.D. Ohio 2000) (Nugent, J.) ("Unjust enrichment arises not only where an expenditure by one party adds to the property of another but also where the expenditure saves the other from expense or loss." . . . plaintiff allegedly "conferred a benefit upon Defendants, *i.e.*, that the City paid for what may be called the Defendants' externalities – the costs of the harm caused by Defendants' [conduct].")).

[44] Plaintiff seeks to streamline the analysis by citing the above-referenced Oklahoma state trial court decision, *State of Oklahoma ex rel. Hunter v. Purdue L.P.*, No. CJ-2017-816 (Okla. Dist. Ct. Dec. 6, 2017), in which the court summarily denied opioid manufacturers' motion to dismiss all counts but one claim, thereby allowing an unjust enrichment claim to proceed on facts similar to those alleged herein. (R. 1008-3; PageID# 24096).

In *Summit County*, the court concluded that the plaintiffs had stated a facially plausible claim for unjust enrichment based on the theory that they had unjustly enriched the defendants by paying the costs of their negative externalities. (R. 1203, PageID# 29055-57, R. 1025, PageID# 24897-24901). Plaintiff's unjust enrichment claim herein is based on the same theory and similar allegations. The parties have not identified, and the court has not found any Oklahoma authority indicating that the courts of Oklahoma would reject this theory. Consequently, the court concludes that the FAC makes out a plausible claim for unjust enrichment.

L. Count X: Civil Conspiracy

Count Ten alleges a civil conspiracy claim against all Defendants. (R. 731, PageID# 17209-11). The Supreme Court of Oklahoma has stated that "[a] civil conspiracy consists of a combination of two or more persons to do an unlawful act, or to do a lawful act by unlawful means." *Brock v. Thompson*, 948 P.2d 279 (Okla. 1997). The *Brock* court set out the essential elements of civil conspiracy: "(1) two or more persons; (2) an object to be accomplished; (3) a meeting of minds on the object or course of action; (4) one or more unlawful, overt acts; and (5) damages as the proximate result." *Id.; see also Schovanec v. Archdiocese of Oklahoma City*, 188 P.3d 158 (Okla. 2008); *Hitch Enters., Inc. v. Cimarex Energy Co.*, 859 F. Supp. 2d 1249, 1268 (W.D. Okla. 2012).

Defendants argue that the civil conspiracy claim fails because Plaintiff has failed to allege a meeting of the minds—an agreement to achieve an unlawful object. (R. 925-1, PageID# 21050-51; R. 928, PageID# 21112). In addition, Defendants argue that there is no underlying intentional and unlawful overt act necessary to satisfy the fourth element articulated in *Brock.* (R. 925-1, PageID# 21051; R. 933-1, PageID# 21278).

Plaintiff has alleged several facts that support the conclusion that all Defendants "together formed an association-in-fact enterprise, the Opioid Supply Chain Enterprise, for the purpose of increasing the quota for and profiting from the increased volume of opioid sales in the United States, including but not limited to creating a market for non-medical use of opioids of epidemic proportions." (R. 731, PageID# 17189, ¶ 382). Plaintiff alleges that all Defendants "jointly agreed to disregard obligations to identify, investigate, halt, and report suspicious orders of opioids and diversion of their drugs into the illicit market" (*Id.* at ¶ 332); concealed their wrongdoing by "collective silence in the face of their duties to speak" (*id.*); and "agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud." (*Id.* at ¶ 390). In addition, the FAC alleges that "for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics" (*Id.* at ¶ 391). As for the "wrongful act" requirement, Plaintiff has sufficiently alleged a RICO claim, which satisfies this requirement under Oklahoma law.

In *Summit County*, the court considered but rejected similar arguments against civil conspiracy claims, namely that the plaintiffs had failed to allege "unlawful acts" and "conspiratorial agreement." (R. 1025, PageID# 24901-04). The court concluded that the plaintiffs therein had plausibly pleaded a claim for civil conspiracy. (R. 1203, PageID# 29039-41). The requirements for civil conspiracy in Oklahoma are similar to those in Ohio.[45] The parties have not identified, and the court has found no Oklahoma authority requiring a different outcome here. Consequently, in accordance with the court's previous ruling in *Summit County*,

[45] Ohio requires "(1) a malicious combination; (2) two or more person; (3) injury to person or property; and (4) existence of an unlawful act independent from the actual conspiracy." *Hale v. Enerco Grp., Inc.*, 2011 WL 49545, at *5 (N.D. Ohio Jan. 5, 2011) (citation and internal quotation marks omitted.)

the court concludes that Plaintiff has sufficiently pleaded a claim for civil conspiracy against all Defendants.

V. Conclusion

For the foregoing reasons, it is recommended that the motions to dismiss be GRANTED in part and DENIED in part. Specifically, it is recommended that Plaintiff's Lanham Act claim contained in Count III be DISMISSED as to all Defendants and that Plaintiff's claims against the Generic Manufacturers are partially preempted to the extent they are based on a narrow category of conduct as explained in Section IV-E, *supra*. In all other respects, it is recommended that the motions be DENIED.

s/ David A. Ruiz
David A. Ruiz
United States Magistrate Judge

Date: April 1, 2019

OBJECTIONS

As set forth in the Court's *Summit County* Orders regarding Objections to Report and Recommendation (R. 1032; 1048), unless otherwise ordered by the Court, Manufacturer Defendants shall coordinate to file a single document addressing objections common to all manufacturing defendants, Generic Manufacturer Defendants shall coordinate to file a single document addressing objections common to all generic manufacturing defendants, Distributor Defendants shall coordinate to file a single document addressing objections common to all distributor defendants, Pharmacy Defendants shall coordinate to file a single document addressing objections common to all pharmacy defendants, and the PEC shall file a single document addressing objections common to all plaintiffs. Defendants filing Objections to the R&R are directed to collaborate with other co-defendants also filing Objections in order to prevent duplicative arguments on the same issue. For example, Manufacturer, Generic Manufacturer, Distributor, and Pharmacy Defendants shall coordinate to avoid objecting to the same issues.

The Court will also accept Responses to the Parties' Objections. All Defendants are directed to coordinate with one another to file a single Response to Plaintiffs' Objections. Plaintiffs are directed to file a single Response that addresses the Objections of all the above-classes of Defendants.

Page limits for the Parties' Written Objections are hereby set to 15 pages for each class of defendant, and 10 pages for Plaintiffs. Alternatively, all Defendants may file a single, omnibus 60-page filing of Written Objections. Page limits for the Parties' Responses are set to 10 pages for both Plaintiffs and Defendants.

Due to the collaboration requirement, the Parties are hereby granted an extension of time to file their Objections and Responses. The Parties' Objections are due no later than 5:00 pm ET on Monday, April 29, 2019. The Parties' Responses are due not later than 5:00 pm ET on Thursday, May 9, 2019.